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Medical Technology and Costs of
THE MEDICARE PROGRAM

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CONGRESS OF THE UNITED STATES
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Foreword

U.S. health care costs have escalated rapidly over the past 15 years, and medical technology is a primary cause of the increase. A major focus of Federal policymakers' concerns about rising health care expenditures is the Medicare program, which pays for hospital and other acute-care health services for over 30 million elderly and disabled Americans.

To aid in congressional efforts to contain Medicare costs, the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment and the Senate Committee on Finance, Subcommittee on Health asked OTA to assess a broad range of mechanisms to limit or reduce Medicare costs related to medical technology without sacrificing the quality of health care delivered.

In addition, the committees requested a study of the proposed use of Diagnosis Related Groups (DRGs) as Medicare's inpatient hospital payment mechanism and several case studies of particular interest to the Medicare program. These are published as separate volumes. This report focuses on the policy mechanisms to limit or reduce Medicare costs related to medical technology but draws from the study of DRGs and the case studies.

This assessment explores the **dual relationship between medical technology and the Medicare program: Medicare policies affect the adoption and use of medical technologies, and the patterns and levels of use of medical technologies significantly affect Medicare costs.** It reviews specific Medicare policies—eligibility, benefits, payment, and beneficiary cost-sharing—that have had an influence on the adoption and use of medical technology. It also examines the contribution of medical technologies to increases in Medicare costs.

The report identifies several possible changes in Medicare policies that could be used to influence medical technology adoption and use and to restrain Medicare program costs. These mechanisms fall into four general categories:

- Medicare's coverage policy for individual medical technologies;
- methods of Medicare payment to hospitals;
- methods of Medicare payment to physicians;
- incentives for the adoption and use of technology that do not directly involve, but may be related to, the Medicare payment mechanism (e.g., encouraging the development of alternative cost-effective health care delivery systems).

This study was ably guided by an advisory panel, chaired by Stuart H. Altman. In addition, a large number of persons in the Federal and State Governments and in the health services research field were consulted. We are grateful for their many contributions. As with all OTA reports, however, the content is the responsibility of OTA and does not constitute consensus or endorsement by the advisory panel or by the Technology Assessment Board. Key OTA staff involved in the assessment were Anne K. Burns, Cynthia P. King, Lawrence H. Miike, Gloria Ruby, and Judith L. Wagner.

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*Until August 1983.
**Since December 1983.
***Since January 1984.
****Until January 1984.

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Glossary of Acronyms

AAMC —Association of American Medical Colleges
AAPCC —average adjusted per capita cost
ACC —American College of Cardiology
ACP —American College of Physicians
ACR —American College of Radiology
ACS —American College of Surgeons
ADAMHA —Alcohol, Drug Abuse and Mental Health Administration (Public Health Service)
AHA —American Hospital Association
AMA —American Medical Association
BC/BS —Blue Cross and Blue Shield Association
CABG —coronary artery bypass graft surgery
CAPD —continuous ambulatory peritoneal dialysis
CBA —cost-benefit analysis
CBO —Congressional Budget Office (U.S. Congress)
CDC —Centers for Disease Control (Public Health Service)
CEA —cost-effectiveness analysis
CEA/CBA —cost-effectiveness analysis/cost-benefit analysis
CEAP —Clinical Efficacy Assessment Project (ACP)
CHAMPUS —Civilian Health and Medical Program of the Uniformed Services
CFA —capital facilities allowance (U.S. Department of Defense)
CMSS —Council of Medical Specialty Societies
CON —certificate of need
CPI —Consumer Price Index
CT —computed tomography scanner
DATTA —Diagnostic and Therapeutic Technology Assessment (AMA)
DHHS —Department of Health and Human Services
DRG —Diagnosis Related Group
ECRI —formerly the Emergency Care Research Institute
ESP —economic stabilization program
ESRD —end-stage renal disease
FDA —Food and Drug Administration (U.S. Department of Health and Human Services)
GAO —General Accounting Office (U.S. Congress)
GPPP —group practice prepayment plans
HCFA —Health Care Financing Administration (U.S. Department of Health and Human Services)
HCPCS —HCFA Common Procedure Coding System
HI —Hospital Insurance (Part A) program
HIAA —Health Insurance Association of America
HIMA —Health Industry Manufacturers Association
HMO —health maintenance organization
ICF —intermediate care facility
ICU —intensive care unit
IOM —Institute of Medicine (National Academy of Sciences)
IPA —independent practice association
JCAH —Joint Commission for the Accreditation of Hospitals
KPMCP —Kaiser-Permanente Medical Care Program
LOS —length of stay
MCR —Medicare cost report
MDC —Major Diagnostic Category
NAFEC —National Association of Freestanding Emergency Centers
NCHCT —National Center for Health Care Technology (Public Health Service)
NCHS —National Center for Health Statistics (Public Health Service)
NCHSR —National Center for Health Services Research (Public Health Service)
NIH —National Institutes of Health (Public Health Service)
NMCES —National Medical Care Expenditures Survey
NMR —nuclear magnetic reasonance
OASH —Office of the Assistant Secretary for Health (Public Health Service)
OCP —Office of Coverage Policy (Health Care Financing Administration)
ODR —Office of Direct Reimbursement (Health Care Financing Administration)
OHTA —Office of Health Technology Assessment (National Center for Health Services Research)
OTA —Office of Technology Assessment (U.S. Congress)
PHS —Public Health Service (U.S. Department of Health and Human Services)
PMC —patient management category
PPO —preferred provider organization
PRO —utilization and quality control peer review organization
ProPAC —Prospective Payment Assessment Commission

PSRO —Professional Standards Review Organization
PTCA —percutaneous transluminal coronary angioplasty
QALY —quality-adjusted life-year
RAHC —Rochester Area Hospitals' Corporation
SLE —systemic lupus erythymatosis
SMI —Supplementary Medical Insurance (Part B) program
SNF —skilled nursing facility
SSOP —second surgical opinion program
TEAM —Technology Evaluation and Acquisition Methods for Hospitals (AHA)
TEFRA —Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248)
TPN —total parenteral nutrition

Glossary of Terms

Allowable costs: Hospital costs that are reimbursable under the Medicare program.

Ancillary technology: Medical technology used directly to support clinical services, including diagnostic radiology, radiation therapy, clinical laboratory, and other special services.

Assignment: An agreement by a physician to bill the Medicare program directly and to accept Medicare's reasonable charge as full payment for his or her services. If the physician does not accept assignment, the patient is billed by the physician and is responsible for the difference between what Medicare will pay and what the doctor charges for a particular service.

Beneficiary cost-sharing: The general set of financing arrangements whereby the consumer must pay some out-of-pocket cost to receive care. (Also see *coinsurance, copayment, deductible,* and *premium.)*

Budget neutrality: Specified by the Social Security Amendments of 1983 (Public Law 98-21) to mean that the aggregate payments for the operating costs of inpatient hospital services in fiscal years 1984 and 1985 will be neither more nor less than would have been paid under the Tax Equity and Fiscal Responsibility Act (Public Law 97-248) for the costs of the same services.

Capital costs: Expenditures for capital plant and equipment used in providing a service. Under Medicare's prospective hospital payment system established by the Social Security Amendments of 1983 (Public Law 98-21), hospitals' capital costs (depreciation, interest, and return on equity to for-profit institutions) are treated as pass-throughs (i.e., are not subject to the new system's controls).

Capitation: A method of paying for medical care on a fixed, periodic prepayment basis per individual. Payment by "capitation" implies that the amount paid by the individual is independent of the number of services that individual has received.

Case mix: The relative frequency of admissions of various types of patients, reflecting different needs for hospital resources. There are many ways of measuring case mix, some based on patients' diagnoses or the severity of their illnesses, some on the utilization of services, and some on the characteristics of the hospital or area in which it is located.

Certificate of need (CON): A regulatory planning mechanism required by the National Health Planning Resources Development Act of 1974 to control large health care capital expenditures. Each State is required to enact a CON law. CON applications by institutions are reviewed by local health systems agencies, which recommend approval or disapproval; they are denied or approved by State health planning and development agencies.

Coinsurance: A form of beneficiary cost-sharing whereby the insured pays a percentage of the total cost of health services.

Conditions of participation: Requirements that a provider must meet in order to be allowed to receive payments for Medicare patients. An example is the requirement that hospitals conduct utilization review.

Copayment: A form of beneficiary cost-sharing whereby the insured pays a specific amount at the point of consumption of health services, e.g., $10 per visit.

Cost-benefit analysis (CBA): An analytical technique that compares the costs of a project or technological application to the resultant benefits, with both costs and benefits expressed by the same measure. This measure is nearly always monetary.

Cost-effectiveness analysis (CEA): An analytical technique that compares the costs of a project or of alternative projects to the resultant benefits, with costs and benefits/effectiveness expressed by different measures. Costs are usually expressed in dollars, but benefits/effectiveness are ordinarily expressed in terms such as "lives saved," "disability avoided," "quality-adjusted life years saved," or any other relevant objectives. Also, when benefits/effectiveness are difficult to express in a common metric, they may be presented as an "array."

CEA/CBA: A composite term referring to a family of analytical techniques that are employed to compare costs and benefits of programs or technologies. Literally, the term as used in this assessment means "cost-effectiveness analysis/cost-benefit analysis."

Coverage: In the Medicare program, coverage refers to the benefits available to eligible beneficiaries, distinguished from payment which refers to the amount and methods of payment for covered services.

Deductible: A form of beneficiary cost-sharing in which the insured incurs an initial expense of a specified amount within a given time period (e.g., $250 per year) before the insurer assumes liability for any additional costs of covered services.

Depreciation: An estimate of the value of consumption of a fixed asset during a specific period of time.

Diagnosis Related Groups (DRGs): Groupings of diagnostic categories drawn from the International Classification of Diseases and modified by the presence of a surgical procedure, patient age, presence or absence of significant comorbidities or complications, and other relevant criteria. DRGs are the case-mix measure mandated for Medicare's prospective hospital payment system by the Social Security Amendments of 1983 (Public Law 98-21).

DRG payment: The system of prospective payment for inpatient services by Medicare which was mandated by the Social Security Amendments of 1983.

Effectiveness: Same as efficacy (see below) except that it refers to ". . . average or actual conditions of use."

Efficacy: The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use.

End-stage renal disease: Chronic renal failure that occurs when an individual irreversibly loses a sufficient amount of kidney function so that life cannot be sustained without treatment intervention. Hemodialysis and kidney transplant surgery are two forms of therapy.

Fee-for-service: A method of paying for medical care on a retrospective basis by which each service actually received by an individual bears a related charge.

Fee schedules: Set amounts of payment to physicians for particular services, generally established by a regulatory body.

Global budgeting: A method of hospital cost containment in which participating hospitals must share a prospectively set budget. Methods for allocating funds among hospitals may vary.

Health maintenance organization (HMO): A health care organization that acts as both insurer and provider of comprehensive but specified medical services by a defined set of physicians to a voluntarily enrolled population paying a prospective per capita fee (i.e., paying by "capitation").

Historical cost depreciation: An estimate of depreciation (see definition) based on the original cost of the fixed asset.

Inpatient care: Care that includes an overnight stay in a medical facility.

Length of stay (LOS): The number of days a patient remains in the hospital from admission to discharge.

Medical technology: The drugs, devices, and medical and surgical procedures used in medical care, and the organizational and supportive systems within which such care is provided.

Medicare: A nationwide, federally administered health insurance program authorized in 1965 to cover the cost of hospitalization, medical care, and some related services for eligible persons over age 65, persons receiving Social Security Disability Insurance payments for 2 years, and persons with end-stage renal disease. Medicare consists of two separate but coordinated programs—Hospital Insurance (Part A) program and the Supplementary Medical Insurance (Part B) program. Health insurance protection is available to insured persons without regard to income.

Medicare carriers: Medicare contractors that compute reasonable charges and make Medicare Part B payments, determine whether claims are for covered services, deny claims for noncovered services, and deny claims for unnecessary use of services.

Medicare contractors: Blue Cross/Blue Shield plans or commercial insurers that perform the Medicare program's claims processing and payment functions at the local level under the policy and operational guidance of the Health Care Financing Administration. (Also see *Medicare carriers, Medicare intermediaries.)*

Medicare Economic Index: The index that the Medicare program uses to determine physicians' prevailing charges, as specified by the Social Security Amendments of 1972 (Public Law 92-603). Specifically, the prevailing charges are calculated by multiplying the 1973 prevailing charges by the current index, which is promulgated annually for the 12-month period beginning July 1.

Medicare intermediaries: Medicare contractors that determine reasonable costs for covered items and services, make payment and guard against unnecessary use of covered services for Medicare Part A payments. Intermediaries also make payments for home health and outpatient hospital services covered under Part B.

Medicare vouchers: A proposed administrative change in the Medicare program in which each eligible person would be allowed a set amount of money to purchase medical care and/or health insurance.

Medigap insurance: Private supplementary medical insurance covering Medicare deductibles and coinsurance.

Outliers: Cases with unusually high or low resource use. DRG outliers are defined by the Social Security Amendments of 1983 (Public Law 98-21) as atypical cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Outpatient care: Care that does not include an overnight stay in the facility in which care is provided.

Part A (Medicare): Medicare's Hospital Insurance program which covers specified inpatient services in hospitals, post-hospital extended care, and home health care services. Part A, which is an entitlement program for those who are eligible, is available without payment of a premium, although the beneficiary is responsible for an initial deductible and/or copayment for some services. Those not automatically eligible for Part A may enroll in the program by paying a monthly premium.

Part B (Medicare): Medicare's Supplementary Medical Insurance program which covers medically necessary physician services, hospital outpatient services, outpatient physical therapy and speech pathology services, and various other limited ambulatory services and supplies such as prosthetic devices and durable medical equipment. Part B also covers home health services for those Medicare beneficiaries who have Part B coverage only. Part B is optional and requires payment of a monthly premium. The beneficiary is also responsible for a deductible and a coinsurance payment for most covered services.

Pass-throughs: In a prospective per case payment system, pass-throughs are elements of hospital cost that are paid on the basis of cost-based reimbursement. For example, under Medicare's new DRG payment system, capital costs, direct teaching, and outpatient services expenses are pass-throughs.

Per case payment: A type of prospective hospital payment system in which the hospital is paid a specific amount for each patient treated, regardless of the number and types of services or number of days of care provided. Medicare's DRG payment system for inpatient services is a per case payment system.

Preferred provider organization (PPO):A contract agreement between providers (physicians or hospitals or both), patients, and insurers that medical care will be delivered at a discounted price as long as the patients use the "preferred providers," i.e., those who are among the contractors.

Premium: A form of beneficiary cost-sharing in which the insured pays a specified amount within a specific time period (e.g., $14.60 per month) as the consideration paid for a contract of insurance.

Prevalence: In epidemiology, the number of cases of disease, infected persons, or persons with disabilities or some other condition, present at a particular time and in relation to the size of the population. It is a measure of morbidity at a point in time.

Price level depreciation: An estimate of depreciation (see definition) based on the current replacement value of the fixed asset.

Procedure (medical or surgical): A medical technology involving any combination of drugs, devices, and provider skills and abilities. Appendectomy, for example, may involve at least drugs (for anesthesia), monitoring devices, surgical devices, and the skilled actions of physicians, nurses, and support staffs.

Professional Standards Review Organizations (PSROs): Community-based, physician-directed, nonprofit agencies established under the Social Security Amendments of 1972 (Public Law 92-603) to monitor the quality and appropriateness of institutional health care provided to Medicare and Medicaid beneficiaries.

Prospective hospital payment: A hospital payment method in which the amount that a hospital is paid for services is set prior to the delivery of those services and the hospital is at least partially at risk for losses or stands to gain from surpluses that accrue in the payment period. Prospective payment rates may be per service, per capita, per diem, or per case rates. Medicare's DRG payment system for inpatient hospital services is a particular form of prospective payment.

"Reasonable and necessary": Criteria used by the Health Care Financing Administration or Medicare contractors to determine what services are eligible for Medicare coverage.

Reasonable charge: The amount (subject to a patient deductible and coinsurance) Medicare will pay for a physician's service. The reasonable charge is the lowest of: 1) the physician's actual charge; 2) the physician's customary charge (the median of charges filed by a physician during the previous year for the service); and 3) the prevailing charge (calculated by multiplying the Medicare Economic Index by the 1973 prevailing charge which is the 75th percentile of the distribution of customary charges of all area physicians in 1972, weighted by the number of times each physician billed for the service).

Recalibration: Periodic changes in relative DRG prices, including assignment of prices to new DRGs.

Retrospective cost-based reimbursement: A payment method in which hospitals are paid their incurred costs of treating patients after the treatment has occurred.

Technology assessment: A comprehensive form of policy research that examines the technical, economic, and social consequences of technological applications. It is especially concerned with unintended, indirect, or delayed social impacts. In health policy, the term has also come to mean any form of policy analysis concerned with medical technology, especially the evaluation of efficacy and safety. The comprehensive form of technology assessment is then termed "comprehensive technology assessment."

Utilization and quality control peer review organizations (PROs): Physician organizations established by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) to replace Professional Standards Review Organizations. Hospitals are mandated to contract with PROs to review quality of care and appropriateness of admissions and readmissions.

1.

Introduction and Summary

A rational man acting in the real world may be defined as one who decides where he will strike a balance between what he desires and what can be done. It is only in imaginary worlds that we can do whatever we wish.

—Walter Lippmann

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1.
Introduction and Summary

U.S. health care costs have escalated rapidly over the past 15 years, and medical technology[1] is a primary cause of the increase. Furthermore, now that controlling health care expenditures has become an issue of national prominence in the public and private sectors, increasing attention is being paid to the financial impact of the use of new and existing medical technologies.

A major focus of Federal policymakers' concerns about rising health care expenditures is the Medicare program, which provides payment for hospital and other acute care health services for over 30 million elderly and disabled Americans. Since 1974, Medicare expenditures have been increasing at an average annual rate of 19 percent (135). Largely because of the Medicare program, the Federal share of national health expenditures has risen continuously since the program's inception in 1966. Medicare expenditures, which represented 48.9 percent of total Federal expenditures for personal health care[2] in 1970, represented 60.8 percent in 1982 (135). In 1982, Federal expenditures under Medicare totaled $52.2 billion. Of that amount, $36.3 billion went for hospital care, and $11.4 billion went for physicians' services (135). Program expenditures in fiscal year 1984 are expected to reach $66.5 billion (340).

Photo credit: E. I. du Pont de Nemours & Co.

In 1982, Medicare had over 30 million elderly and disabled beneficiaries

Medicare's beneficiaries, elderly and disabled Americans, are on average sicker than the general population. Furthermore, they are disproportionately high users of health care services in general and medical technology in particular. Every class of medical technology—with the exception of obstetrical, pediatric, and possibly preventive interventions—is on average applied more often to Medicare beneficiaries than to the population as a whole. In 1980, those over the age of 65 accounted for 11.2 percent of the population but 31.4 percent of health care costs (265). Both percentages are expected to rise significantly in the future because of the aging of the U.S. population.

To aid in congressional efforts to contain Medicare costs, the House Committee on Energy and Commerce and its Subcommittee on Health and the Environment and the Senate Committee on Finance, Subcommittee on Health asked OTA to assess a broad range of mechanisms to limit or reduce Medicare costs related to medical technology. In addition, they requested a study of the proposed use of Diagnosis Related Groups (DRGs) as Medicare's inpatient hospital payment mechanism and several case studies of particular interest to the Medicare program. These are published as separate volumes. This report focuses on the policy mechanisms to limit or reduce Medicare costs related to technology but draws from the study of DRGs and the case studies.

The present assessment explores **the dual relationship between medical technology and the Medicare program: Medicare policies affect the adoption and use of medical technologies, and the patterns and levels of use of medical technologies significantly affect Medicare costs.** It reviews specific Medicare policies—eligibility, benefits, payment, and beneficiary cost-sharing policies—that have had an influence on the adoption and use of medical technology. It also examines the contribution of medical technologies to increases in Medicare costs.

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[1] OTA defines medical technology as the drugs, devices, and surgical and medical procedures used in medical care, and the organizational and supportive systems within which they are provided.

[2] Personal health care expenditures are national health care expenditures minus administrative costs.

OTA identified several possible changes in Medicare policies that could be used to influence medical technology adoption and use and to restrain Medicare program costs. These mechanisms generally fall into the following categories:

- changes in Medicare's coverage policy for specific technologies;
- changes in the methods of Medicare payment to hospitals;
- changes in the methods of Medicare payment to physicians; and
- approaches to changing the incentives for the adoption and use of technology that do not directly involve, but may be related to, the Medicare payment mechanism (e.g., encouraging the development of alternative cost-effective health care delivery systems).

Because of the vast number of medical technologies being developed or used and the decentralized administration of the Medicare program, technology-specific approaches are likely to be of limited value in containing Medicare costs.[3] For that reason, broader approaches, many of which involve the use of hospital or physician payment mechanisms to change providers' or consumers' financial incentives to use medical technology, are generally considered the major means by which the cost-containment objectives of the Medicare program might be achieved. The change in Medicare's inpatient hospital payment system—from retrospective, cost-based payment to prospective, per case payment based on DRGs, as mandated by the Social Security Amendments of 1983 (Public Law 98-21)—provides a striking example of such an approach.

Other broad approaches do not involve the payment mechanism directly but are usually considered in conjunction with payment mechanism changes to alter the incentives for technology use. These include stimulating competition among providers of health care by encouraging the development of alternative sites or organizations (e.g., health maintenance organizations) of health care delivery. They also include administrative changes in the Medicare program (e.g., merging Parts A and B of Medicare) for the purpose of changing incentives for technology adoption and use.

There are two additional broad approaches to containing Medicare costs, but they are not discussed extensively in this report. The first approach is simply to limit the amount of money available for Medicare. Applying such a financial squeeze would give providers and patients strong incentives to adopt and use technologies efficiently. However, applying such a limitation to the Medicare program alone, while saving Federal dollars, would likely either shift costs to the private sector or result in Medicare beneficiaries' reduced access to certain technologies. The second approach is to use the conditions of participation for Medicare providers (i.e., requirements providers must meet in order to be eligible to receive payment from Medicare) to change the incentives for technology use.

Several points should be kept in mind while reading this report. These points are not presented in order of importance, primarily because the issues involved are intertwined.

First, the impact of medical technologies on Medicare costs, or health care costs in general, should not be assessed in isolation from the effect that such technologies have on quality of care. The impact of cost-containing measures on both quality and access is one of the most difficult policy issues to be faced, because the Medicare program was instituted to increase elderly persons' access to acute care services. In order to control Medicare costs in the long run, some restrictions on quality or access are likely to be necessary. Unfortunately, the rapid rate of growth in health or Medicare expenditures cannot be stemmed simply by eliminating technologies that do not provide any benefit, because most technologies do provide some benefit, however small or costly the benefit may be (25).

Nevertheless, **there is substantial evidence to suggest that inappropriate use of medical technology is common and raises Medicare and health system costs without improving quality of care.** Many surgical procedures seem to be overused in the United States compared to other countries (26). Laboratory examinations and other diagnostic tests are used at high rates and at times when not indicated by the suspected conditions (90,120,296). Lengths of stay in the hospital are higher in many cases than can be justified by medical evidence of benefit (350). Thus, one way to reduce Medicare costs is to encourage the appropriate use of new and existing medical technologies.

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[3] Technology-specific approaches may be particularly valuable, however, in enhancing the adoption of socially valued technologies that may be cost-raising.

Second, there are interactions between Medicare and the rest of the U.S. health care system. Because of its size and scope, and because other third-party payers often follow Medicare's example, Medicare's policies and procedures affect all aspects of health care delivery, including financing, administration, organization, and personnel. Furthermore, the program affects the content and costs of health care by its influence on the development, adoption, and use of medical technology.

Nevertheless, it is important to keep in mind that **the Medicare program is only one of many public and private institutions that influence the development and diffusion of medical technology.** Other important influences are the Food and Drug Administration, the National Institutes of Health, manufacturers of drugs and medical devices, hospitals, private health insurers, and professional medical societies. The long-term costs of the Medicare program are linked with those of the overall health care system, and the leverage of using Medicare-specific policies to achieve Medicare cost-containment objectives may be limited.

Third, reimbursement policy by Medicare and other third-party payers has contributed to the rapid adoption and often excessive use of medical technology. Therefore, policymakers have looked to changes in reimbursement policies to alter the financial incentives for providers and consumers to use medical technology. **However, reimbursement is only one of several factors that contribute to the tendency to adopt and use medical technology.** Other factors include public demand for sophisticated technologies, the desire of physicians to do as much as possible for their patients, competition among hospitals to achieve quality and prestige so as to attract patients and physicians, the fear of malpractice suits, and uncertainties about what constitutes appropriate use.

Fourth, because of spillover effects from one part of Medicare to another, policy mechanisms involving only one part of the Medicare program may have serious limitations in terms of containing Medicare costs or affecting technology adoption and use. Medicare's DRG hospital payment system, for example, excludes physicians' services and outpatient care. These exclusions not only provide incentives for the shifting of costs out of inpatient hospital settings but leave physicians' incentives to use medical technology unaffected. Any cost-containment effort must take into account the fact that physicians play a central role in determining what services are provided to patients in both hospital and other settings.

Fifth, what constitutes rational and appropriate adoption and use of medical technology depends on whether the question is being viewed from a societal perspective, from the perspective of the Medicare program, or from the perspective of individual providers or patients. A rational decision to adopt or use a medical technology is a decision based on the consideration of costs and benefits. A decision by hospitals or physicians to adopt a medical technology that improves the quality of care provided to patients may also raise the costs of the Medicare program. From the perspective of the providers or patients, such a decision may be entirely rational. However, the costs and benefits to providers and patients are different from those to the Medicare program. Thus, unless the marginal increase in the benefit of improved patient care justifies the marginal increase in costs to the Medicare program, the decision may not be rational for Medicare. Furthermore, what is rational and appropriate from the standpoint of Medicare is not necessarily rational and appropriate from the standpoint of society as a whole.

Sixth, the social and political climate today is quite different from that in 1965, and now that Medicare's goal of improving access to health care for the Nation's elderly has been largely achieved, the primary focus of policymakers is on containing Medicare costs. The principal intent of the 1965 legislation establishing the Medicare program under Title XVIII of the Social Security Act (Public Law 89-97) was to increase elderly Americans' access to acute care medical services by removing financial barriers, particularly to hospitalization (317). There was far less concern about the cost of services than about the problem of access. The concern about access was also prominent in 1972, when eligibility was extended by Congress to disabled persons and people with end-stage renal disease (ESRD). More recently, however, the costs of the program have soared, and the pressures for cost containment have increased. Thus, the challenge that remains for Federal policymakers today is to solve the problem of controlling Medicare costs without diminishing past success.

SCOPE OF THE REPORT

This report examines medical technology's impact on Medicare costs and Medicare's past and future impact on the development and diffusion of medical technology. Medical technology is the major component of medical care. The incentives that govern the provision of medical care services work in the same direction (and are of the same magnitude) as those that govern the adoption and use of medical technology. In this report, therefore, the term "medical technology" is sometimes used synonymously with "medical care" or "medical services."

The bulk of the increases in health and Medicare costs in the past 20 years is attributable to factors other than changes in the patterns and levels of use of medical technology, such as general wage and price inflation and growth in the size of the U.S. population age 65 and over. A detailed examination of these factors, however, is beyond the scope of this report.

The policy options presented in this report emphasize controlling costs by changing the incentives for technology adoption and use, primarily through Medicare's hospital and physician payment mechanisms. The report does not discuss changes in Medicare eligibility or in the broad Medicare benefit package. A serious problem needing attention that this report does not address is the widening gap between the Medicare beneficiary population's needs and the benefit package actually provided. Medicare's benefit package was modeled after insurance plans of the early part of the century, when acute illness was the primary concern and when most patients either got well or died rather quickly (317). Some services critical to chronic disease—preventive measures, custodial or long-term care, drugs in outpatient settings, and many rehabilitative services—were excluded from covered benefits. Ironically, as Medicare has achieved its objective of improved access to acute care services and mortality rates among the Nation's elderly have decreased, morbidity from chronic diseases has increased because of the aging of the population. Thus, elderly individuals who cannot afford uncovered services remain an underserved segment of the population.

This report does not consider how much money is appropriate to expend on Medicare beneficiaries. That decision is essentially a political one. As noted earlier, one way to cut Medicare costs, and change the incentives for technology use and adoption, is simply to cut money out of the system. The options presented in this report could be implemented regardless of the political decisions about how much money is appropriate to spend.

ORGANIZATION OF THE REST OF THE REPORT

The rest of this chapter presents a summary of the report and briefly lists the issue areas for which there are policy options. The body of the report is organized in three parts.

Part One presents information on the interactions between medical technology and Medicare. Chapter 2 discusses Medicare's impact on the adoption and use of medical technology. After presenting a brief overview of general policies, the chapter describes the specific Medicare policies that have been important to the development and diffusion of medical technology. In chapter 3, the emphasis turns to medical technology's impact on Medicare costs. The chapter examines the patterns of medical technology use experienced by the Medicare population compared to the general population. Then, it reviews the evidence on the contributions of medical technology to general health care costs and to Medicare costs. Those contributions are discussed in the aggregate and with respect to particular technologies.

Part Two contains chapters providing information about policies that have been and could be taken to restrain the costs of medical technologies in the Medicare program. Chapter 4 provides an overview of the issues underlying the remaining chapters. Chapter 5 reviews Medicare's coverage policy and process for individual medical technologies and discusses possible linkages between technology assessment and coverage for the purpose of containing costs. Chapters 6 through 8 examine broader policies that have impacts on medical technology adoption and use. Chapter 6 analyzes the implications for medical technology of current and potential methods of hospital payment. Chapter 7 presents a similar analysis of physician payment methods. It also includes a discussion on how physicians influence technology use and how physician cost consciousness may be enhanced. Chapter 8 presents information on broad approaches (those other than direct Medicare payment changes) to change the incentives for medical technology adoption and use, primarily by stimulating competitive behavior among providers.

Part Three (ch. 9) presents the main findings and policy options of the study, organized by issue area.

Appendix A describes the method used by OTA to conduct the assessment and lists the background papers (including case studies) prepared in conjunction with the project. Appendix B contains the acknowledgments and the membership of the Health Program Advisory Committee. Appendix C provides information on public and private technology assessment activities. Appendix D is a descriptive overview of selected alternatives to traditional health care delivery. Appendix E presents the results of a survey of Medicare contractors.

A series of case studies was used to provide specific examples of issues and problems (see app. A). The report makes reference to the case studies throughout. The full cases themselves are printed as separate volumes of OTA's *Health Technology Case Study Series*. In addition, a technical memorandum entitled *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* was prepared as part of this study and published in July of 1983.

Finally, a summary booklet is available. It contains information similar to the following summary section and the chapter on policy options.

SUMMARY

Medicare Policies Affecting Medical Technology

The very existence of Medicare and other third-party payers expands the market for medical technologies and influences the quantity and kinds of medical technologies that are used and the settings in which they are used. Since the enactment of the Medicare program in 1965, a great deal of legislation has been passed with the *purpose* of curbing the escalation in Medicare's costs and controlling the diffusion of medical technology. To date, such efforts have been largely ineffective. Indeed, Medicare's policies concerning eligibility, benefits, and payment have acted to promote technology adoption and use.

Medicare's *eligibility* policy has made more medical technology available to millions of the Nation's aged and disabled people. When the program began in 1966, 19.1 million people aged 65 and over were eligible to enroll. By 1982, the number of Medicare enrollees had increased to 29.5 million. The increase in the size of the Medicare population is due largely to the growth in the size of the elderly population, but some of it reflects the extension of Medicare eligibility to people with disabilities and ESRD on July 1, 1973.

Medicare's *benefit* policy has had a profound effect on the types and location of modern medical technologies. The Medicare law specifies broad categories of benefits for which the program will pay under two parts: Part A, the Hospital Insurance program, and Part B, the Supplementary Medical Insurance program.[4] The law excludes most preventive services and certain other services, such as custodial and long-term care. Medicare's benefit package has undergone few major changes since the program's beginnings.

Although the Medicare program covers a variety of services in a variety of settings, its benefit package is concentrated primarily on acute care technologies provided in institutional settings, particularly those provided as inpatient hospital services. In 1982, 66.3 percent ($34.5 billion) of Medicare's $52.2 billion in payments was for inpatient hospital services. **There are numerous incentives inherent in Medicare's benefit policy to provide too many of some kinds of medical technologies and too few of others.** Coverage of some technologies (e.g., medical devices, drugs), for example, varies according to the characteristics of the technology, of the user, and of the setting in which the technology is used. In some cases, as in treatment for alcoholism, Medicare's benefit policy has encouraged the development of a technology in an inpatient setting, despite the fact that treatment in other settings may be as effective and is certainly less costly (348). Medicare's exclusion of benefits for some technologies, including assistive communications devices (351), has had an unfavorable influence on their development and diffusion.

A dramatic specific example of how Medicare's eligibility and benefit policies have affected the development and diffusion of costly medical technologies is provided in the case of technologies used to treat ESRD. People with ESRD require some form of dialysis or kidney transplantation to prolong their lives. In 1972, before Medicare eligibility was extended to persons with ESRD, about 10,000 persons were receiving hemodialysis. By 1980, following the extension of eligibility, 50,000 were being dialyzed (359). There was also a significant increase in kidney transplantation following implementation of the ESRD program (359). Currently, an estimated 93 percent of the U.S. population with ESRD are Medicare beneficiaries (195). Thus, Medicare policies can be clearly identified as a major influence on the diffusion of the technologies used in the treatment of ESRD.

Photo credit: National Kidney Foundation, Washington, D.C.

Medicare policies are a major influence on the development and diffusion of hemodialysis and other technologies used in the treatment of ESRD

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[4] Part A benefits include inpatient hospital care, post-hospital extended care services, home health services, and as of Apr. 1, 1982, inpatient alcohol detoxification services. Part B benefits include medically necessary physician services, outpatient hospital services, outpatient physical therapy and speech pathology services, home health services for those not eligible for Part A, and various other limited ambulatory services and supplies (e.g., prosthetic devices and durable medical equipment).

Medicare's payment policies have had the most profound effect on medical technology adoption and use of any of the program's policies. For many years, Medicare has paid hospitals and other institutional providers on the basis of reasonable cost and paid physicians and other noninstitutional providers reasonable charges on a fee-for-service basis. Under both payment methods, providers receive more reimbursement when they use more medical technology. Thus, these payment methods offer providers little deterrent to the increased use of technology and little incentive to choose less costly technology.

Although Medicare's hospital payment system is now in the process of change,[5] 17 years of cost-based hospital payment have shaped the health care system today. The original Medicare legislation left the specific method of determining reasonable cost to administrative decisions. The method adopted was very liberal in allowing hospitals considerable discretion in calculating the costs attributable to Medicare (104). Thus, because hospitals have been assured of reimbursement by Medicare and by other third-party payers, they have had no financial reason not to spend money on medical technology, especially on socially valued technology.

Medicare's method of paying physicians has changed little since Medicare was enacted, although minor restraints have been imposed on the rate of increase of physicians' payment levels. Most physicians' incomes are determined by the number and intensity of services delivered and the fee received for each service. The use of technology by fee-for-service physicians is sensitive to the additional revenue they receive (229).

In addition, although not intrinsic to the fee-for-service payment method, physician payment levels that Medicare has established for complex and expensive medical technologies are usually disproportionately high (235). In most instances, the reimbursable charge for a technology was established at an early point in the technology's history. Although subsequent technological advances and higher rates of utilization may have substantially reduced the time, judgment, skill, and cost required to use the technology, this change is not reflected in the physician's fee or Medicare's reimbursement level. Furthermore, the existing payment system provides incentives for the use of "technology-intensive" medical care. Under current fees, what are sometimes referred to as "technology-oriented" services, such as diagnostic tests and surgical procedures, are valued higher than "cognitive" services, such as taking medical histories and counseling.

Medicare's *beneficiary cost-sharing* provisions were the only measures specifically included in the original legislation to help moderate the unnecessary utilization of services. Although there is little empirical evidence concerning the effect of deductibles, copayments, and coinsurance on the use of medical technology specifically in the Medicare program, it is generally believed that such cost-sharing has had little impact on technology use. Supplementary health insurance ("Medigap") is used extensively by Medicare beneficiaries, and it often substantially diminishes or eliminates the burden of these cost-sharing requirements. Premium payments, another form of cost-sharing, are clearly not an obstacle to the use of services (28,253).

The Impact of Medical Technology on Medicare Costs

Changes in the kinds of medical technologies available and changes in the patterns of use of technologies already available continually influence health care costs—at times moderating cost increases and at times exacerbating them. How medical technology contributes to health and Medicare costs is a question that can be addressed either in the aggregate or with respect to particular technologies or classes of technologies.

The question from the aggregate perspective is whether changes in medical technology use as a whole have raised or reduced health care or Medicare costs and, if so, by how much. The aggregate perspective is useful, because it puts technology's relationship to costs into a policy perspective.

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[5] Medicare's hospital payment method was changed by the Social Security Amendments of 1983 (Public Law 98-21), which mandated the phasing in beginning in October 1983 of a prospective per case inpatient hospital payment system based on Diagnosis Related Groups (DRGs). The implications of DRG hospital payment are discussed in a following section.

The most widely used approach to estimating technology's aggregate contribution to health care costs is to separate the change in total expenditures for health care into its component parts: population or enrollment changes, overall wage and price inflation, wage and price inflation in medical care in excess of general inflation, and changes in service intensity.[6] Changes in technology use are included in the latter two measures, although these measures also reflect other factors.

Using this general approach, OTA estimates that **increases in service intensity (labor and nonlabor inputs) per capita accounted for 24 percent of the 93-percent increase in per capita hospital costs from 1977 to 1982.** The increase in service intensity is due in part to an increase in the hospital admission rate (a 5-year increase of 2.1 percent), but the overwhelming part of the increase is due to the provision of a greater quantity of services per hospital admission. Moreover, OTA's empirical and literature analysis supports the general conclusion that **changes in service intensity have contributed substantially to the growth in hospital costs over the past 20 years.**

Increasing intensity of care appears to be a less important source of expenditure inflation in total personal health care expenditures in the United States than it is for the hospital sector alone. **The combined effect of increasing intensity of care and increasing health care prices in excess of the Consumer Price Index accounts for only about 16 percent of the growth in per capita personal health care expenditures between 1977 and 1982. During that 5-year period, however, these two technology-related components of cost together increased real per capita personal health expenditures at an average annual rate of 2.8 percent.**

It is possible to account for the components of Medicare cost increases, but the interpretation of the estimates is even more clouded than is the interpretation of increases in general health care costs. Changes in program eligibility or in covered benefits can lead to dramatic changes in measured service intensity that have little to do with changes in medical technology but instead represent a shift in the burden to payment for services already available and used. Changes in per capita service intensity do indicate how much more or less Medicare is paying for now than at some earlier date. Between 1977 and 1982, Medicare expenditures per enrollee increased 107 percent. OTA's analysis indicates that **nearly 30 percent of the increase in Medicare costs per enrollee from 1977 to 1982 can be attributed to increased use of covered services (25 percent) and increased medical prices in excess of general inflation (3 percent).**[7]

Although none of the approaches to measuring technology's aggregate contribution to health care or Medicare costs is entirely satisfactory, **taken as a whole, the available evidence leads to the conclusion that health care costs have increased in part because more is being done for patients today than ever before.** More and better trained personnel, more procedures, more drugs, and more and higher priced equipment, materials, and supplies are being used in the delivery of health care to Medicare patients and to the population as a whole. So far, the trend toward "more" does not appear to be abating. It is not just at the margin, however, that there is an opportunity to reduce Medicare costs. There are many opportunities to save health and Medicare costs by altering longstanding patterns of use of medical technology.

Furthermore, the aggregate approach to estimating medical technology's contribution to health care or Medicare costs is limited, because it ignores the patient benefits associated with cost increases or decreases, it does not take into account the underlying reasons for changes in medical decisions or practices, and it does not show that cost-saving and cost-raising changes in technology are not scattered evenly across illnesses. **Summary statements about technology's net influence on health care or Medicare costs mask the**

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[6] "Service intensity" refers to the quantity of inputs that go into producing a given unit of health care. These inputs include labor, supplies, materials, and equipment used in the provision of care. Service intensity is associated with, but not *identical* to, medical technology use.

[7] The percent due to medical price inflation may be overstated, and the service intensity percentage correspondingly understated, because the amount Medicare actually pays for services (i.e., the effective price) probably lies somewhat below stated prices.

rich assortment of ways in which changes in medical technology shape the health care system, the population's health status, and its costs.

Thus, in order to provide insight into the underlying reasons for change in medical decisions or practices and to highlight the extent to which the costs of the Medicare program are altered by new technologies, OTA examined seven specific technologies first introduced in the 1960's or 1970's: coronary artery bypass surgery, the drug cimetidine, therapeutic apheresis, pneumococcal vaccine, intensive care units, total parenteral nutrition therapy, and kidney dialysis.

All seven of the technologies have clear patient benefits—in some cases, they are life saving—but for all of the technologies, there is controversy about the most appropriate indications for use. Two of these technologies have been or may be cost saving to Medicare, but five of them have raised or have the potential to raise Medicare costs, in some cases significantly. Above all else, these technologies illustrate how exposed the Medicare program is to changes in medical technology that are largely beyond its control. The challenge to Medicare in the face of new technologies that offer both patient benefits and higher costs is how to encourage the most cost-effective use of the most cost-effective technologies. The overall remaining issue is how Medicare policy can be structured to bring about more cost-effective use of both existing and new medical technologies.

Overview of Areas for Change in Medicare

OTA's discussion of potential areas for change under Medicare is organized in two parts, corresponding to the two types of policy mechanisms discussed previously. The first part—policies directed at individual technologies—explores linking Medicare's coverage policy and technology assessment to contain costs. The second part—policies providing broad incentives to encourage appropriate adoption and use of technologies—is divided into three sections: hospital payment, physician payment, and alternative or systemwide approaches to changing incentives.

Specific Technologies: Linking Coverage Policy and Technology Assessment To Contain Costs

A potential method of containing Medicare costs is by influencing the diffusion (i.e., adoption and use) of medical technologies. It is generally agreed that Medicare's coverage policy—policy that governs the eligibility of services (technologies) for payment—has influenced decisions about the purchase of some expensive, visible medical technologies. The precise relationship between coverage policy and adoption of other kinds of technologies or *use* of any technologies remains speculative.

Although Medicare and other insurance plans designate broad categories of services, such as inpatient services, as being covered, or eligible, for payment, specific technologies, with few exceptions, require individual coverage decisions. Medicare coverage policy for particular technologies not mandated by law has been decided on a case-by-case basis according to Section 1862 of Title XVIII of the Social Security Act. Section 1862 prohibits Medicare payment for items and services that are "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Medicare has refrained from establishing a definitive interpretation of "reasonable and necessary" and has relied on a loosely structured and decentralized mechanism to determine whether a technology is covered. The criteria used to determine if a technology meets the broad statutory language of "reasonable and necessary" are: 1) general acceptance as safe and effective, 2) not experimental, 3) medically necessary, and 4) provided according to accepted standards of medical practice in an appropriate setting. Traditionally, coverage policy has been made in light of Medicare's principles of not interfering with the practice of medicine and assuring beneficiaries a free choice of providers.

Some coverage decisions are made at the national level by the central Health Care Financing Administration (HCFA) office, while others are made by regional HCFA offices. Most of the decisions, however, are made by Medicare contractors, called intermediaries and carriers, who perform the Medicare program's claims processing and payment function at the local level under the policy and operational guidance of HCFA. Although the details vary, the coverage process is the same at the national level or at the contractor level. First, new technologies and new uses of covered technologies are identified. Second, a decision is made about covering the identified technology for Medicare payment. The decisionmakers (contractors or HCFA) may receive advice, which usually involves an evaluation of the safety and effectiveness of the technology. The final step is implementing the coverage decision.

Because of the general language of Section 1862 and the absence of regulations or guidelines that implement the section, Government officials and Medicare contractors have had considerable latitude in determining which technologies are to be covered for reimbursement. Contractors vary widely in their identification of uncovered technologies, their decisions about the coverage of specific technologies, and their implementation of national coverage decisions (54,86,143,353). As a result, some technologies may be covered and paid for in one area and not in another. There is no national or local listing of procedures that are not covered (163).

Problems pertaining to the administration of the coverage process that need attention include: 1) the inadequate identification of emerging and outmoded technologies for coverage decisions; 2) the lack of uniformity in implementing national coverage decisions; 3) the timelag involved in the coverage process, including technology assessment; 4) the complex coding system and proliferation of codes; and 5) the incomplete dissemination of information. These problems all potentially raise Medicare's costs, although some of them (e.g., numbers 2, 3, and 5) may actually decrease Medicare expenditures.

Of particular interest to cost-containment efforts is Medicare's policy of not explicitly considering cost or cost-effectiveness information in making coverage decisions. Also of interest is the fact that Medicare has refrained from a policy of limiting coverage of particular technologies to restricted circumstances (e.g., institutions offering specific services or having specialized equipment) and to physicians with specific skills. Although the notion of limiting coverage to selected sites and providers has gained importance with the increasing development of sophisticated technologies that require particular expertise, Medicare's principles of refraining from interfering with medical practice and assuring beneficiaries a free choice of providers appear to have limited its application. On the other hand, Medicare does limit coverage of some technologies to appropriate medical conditions. For example, therapeutic apheresis is currently covered for six disease indications.

In theory, one way to use coverage policy to assist in containing Medicare costs would be to include cost criteria in technology assessments. Cost-benefit analysis (CBA) and cost-effectiveness analysis (CEA) are formal analytical techniques for comparing the positive and negative consequences of alternative ways of allocating resources (353). The methodological strengths and weaknesses of CBA/CEA and the potential for expanding their use in coverage decisions was discussed in OTA's 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology*. A methodological issue of particular importance to beneficiaries of the Medicare program is whether to include discounted future medical care costs (due to longer lifespans for patients resulting from the use of medical technology) as a direct cost of a technology.

Incorporating cost criteria into an assessment, however, would not necessarily lead to the identification of cost-saving technology. Achieving the objective of identifying technologies that save or raise costs to Medicare before they become established in medical practice is problematic. The technical complexity of determining the cost effects of emerging and new technologies is compounded by the problem of defining a cost-saving or cost-raising technology. Differences in perspective impede arrival at a universal definition of a cost-saving or a cost-raising technology.

A new issue for Medicare is how to coordinate coverage policy with the DRG hospital payment system. Although the coverage process and the process of adjusting DRG rates share a similar "approval for payment" function, they differ in that a coverage determination focuses on specific technologies, while adjusting DRG payment rates focuses on the larger entity of a diagnostic group, which includes particular technologies. Moreover, the DRG rate adjustment process must include issues of cost as an integral issue, while the coverage process at present does not consider cost issues. **Nonetheless, the technology assessments performed for the coverage and DRG rate adjustment processes no doubt will have similarities and their coordination should be encouraged.**

Medicare Hospital Payment and Medical Technology

The retrospective, cost-based hospital reimbursement system under which Medicare operated from 1966 until fiscal year 1983 was significantly altered first by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) and then by the Social Security Amendments of 1983 (Public Law 98-21). The latter mandated the phasing in over a 3-year period of a prospective, per case hospital payment system based on DRGs. The new prospective payment system for inpatient operating costs places hospitals at financial risk but also enables them to keep whatever surpluses can be generated.

Although capital, outpatient, and direct teaching expenses remain pass-throughs,[8] Medicare's DRG hospital payment system has radically changed the financial incentives for the adoption and use of specific medical technologies in hospitals.[9] Hospitals now have a financial incentive to increase hospital admissions and decrease lengths of stay. Some patients may be admitted unnecessarily, others may be discharged too early, and some may not get all the elective care in one hospital stay. Thus, hospital admissions and readmissions will need to be monitored.

The DRG payment system also provides hospitals with incentives to reduce the number and cost of ancillary services. Prior to the implementation of DRG payment, hospital administrators had financial reasons to encourage physicians to use available technologies. Now, hospital administrators will need to gain the support and cooperation of their physicians in order to keep their inpatient care within the price range of DRG payments. Under the new system, hospital administrators are likely to discourage physicians from using many high-cost technologies. **In some cases, the substitution of low-cost technologies for high-cost technologies may result in a decline in quality of care. Thus, quality of care remains an important issue under DRG payment.** Congress has provided some control over quality of care by mandating the utilization and quality control peer review organizations (PROs). Hospitals must have signed agreements with these organizations in order to receive Medicare payments. One of the responsibilities of the PROs will be to monitor the potential admission/discharge/readmission problem.

Despite the recent establishment of the DRG hospital payment system, it is quite possible that changes in hospital payment by Medicare will be actively considered in the future. Part of the reason is that pressure for cost containment at the Federal level may continue, and part is that individual States may enact hospital cost control systems in which Medicare will agree to participate. Alternative approaches that have been suggested or applied by public or private payers and that might be considered for implementation by Medicare generally fall into four major categories:

- alternative hospital prospective payment methods or modifications of Medicare's DRG hospital payment system,
- capital payment methods,
- limited provider contracts, and
- increased patient cost-sharing for hospital services.

Congress has adopted DRGs for the Medicare hospital payment system, but improvements of DRGs and of the payment system should be pursued. Case-mix classification systems with more desirable properties than DRGs may become available in the future. **Innovations in medical devices, drugs, and medical techniques that raise the quality of care for the Medicare population**

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[8] Pass-throughs are those elements of cost that are not part of the prospective payment system.

[9] OTA's technical memorandum entitled *Diagnosis Related Groups (DRGs) and the Medicare program: Implications for Medical Technology* (343) provides a detailed analysis of these incentives.

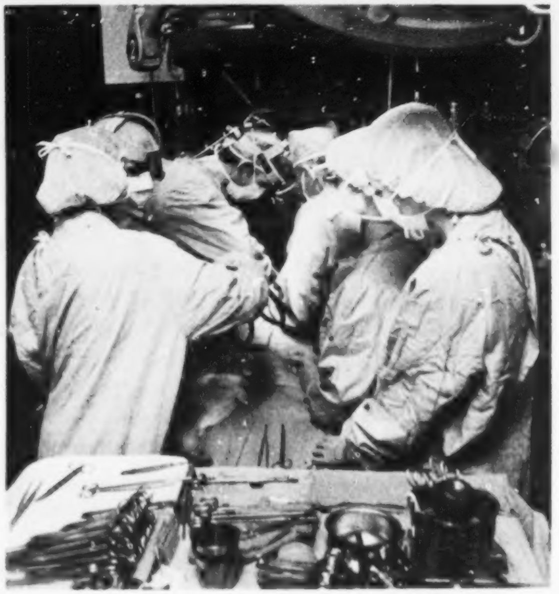

Photo credit: University of Utah Medical Center

Updating the DRG hospital payment system will be necessary to encourage the adoption of technologies that raise the quality of care provided but also raise hospital per case costs

but also increase hospital per case costs may not be readily adopted unless DRG payment rates are updated. Refinements of Medicare's DRG-based hospital payment system are anticipated in light of the series of congressionally mandated studies and the charge to the Prospective Payment Assessment Commission to recommend changes in DRG relative weights and categories. Other approaches to prospective payment of hospitals are certainly possible, and the current Medicare law encourages States to experiment with these as part of all-payer systems. Innovative prospective payment methods such as per capita hospital payment and areawide global budgeting may hold promise in some areas.

How Medicare will pay for hospitals' investments in capital plant and equipment under DRG payment is an issue that has yet to be resolved. Traditionally, Medicare has reimbursed hospitals for interest and historical cost depreciation expenses associated with all capital equipment. This payment method has increased hospitals' demand for capital but has also made it difficult and costly for some hospitals to obtain additional debt financing. Currently, under DRG payment, capital costs are treated as pass-throughs (i.e., reimbursed, as they always have been, as they are incurred with no limit on the amount that a hospital can be paid). **Of particular concern with a capital cost pass-through under DRG payment is the incentive for hospitals to adopt expensive capital equipment that reduces operating costs but raises total costs per case.** Congress has recognized that capital costs are still a problem for Medicare, and Public Law 98-21 requires the Department of Health and Human Services to study how capital costs should be paid in connection with the DRG hospital payment system.

Two possible alternatives to the pass-through are to incorporate a flat rate for hospital capital into the DRG rates and to build hospital-specific capital allowances into the DRG system. Although the flat rate approach is generally more efficient than pass-through capital payment, it does raise questions of fairness among hospitals and equity of access to medical technologies among patients. In a flat rate payment system, hospitals that in the past had lower ratios of capital to operating costs would receive more payment than they had in the past. The hospital-specific approach would tend to reward those hospitals that were most highly capitalized in the past, leaving those with less capital forever to receive lower payments.

Two additional approaches to affecting the use of medical technologies through hospital payment are limited provider contracting and increased beneficiary cost-sharing for hospital services. Both methods have significant limitations. Limited provider contracts for hospital care[10] would involve selecting certain hospitals for the provision of inpatient care to Medicare beneficiaries. Overall, although contracting may save program dollars, it represents an abandonment of the principle of assuring beneficiaries freedom of choice of providers on which Medicare was built and forces subsidies of hospital care from other payers.

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[10] Currently, State Medicaid agencies may apply for waivers from the freedom-of-choice provision of the Social Security Act. Most waivers to date have been for case management systems that restrict the providers from whom a Medicaid beneficiary can obtain primary care, although California has adopted an approach of contracting with hospitals for inpatient care for Medicaid beneficiaries.

Medicare Physician Payment and Medical Technology

Any cost-containment effort must take into account the fact that physicians are key decisionmakers with respect to the use of medical technologies. Physicians determine the amount of medical services to be provided, when patients need hospitalization, and when they need other types of care.

There is substantial evidence to suggest that inappropriate use of medical technologies is common and raises costs without improving quality of care. Such excessive use exists within the norms of medical practice and across the spectrum of technologies available to physicians. Physicians' habitual behavior can cause excessive use of medical services. Until recently, medical education trained physicians to do all they could for their patients' well-being without concern for the cost. In response to restraints in their payment, physicians have changed the number and mix of services they provide. The practice of defensive medicine in response to fears of lawsuits may also increase unnecessary use, and thus cost, of medical technologies.

Physician behavior with regard to the use of medical technologies may be modified by financial incentives, educational programs, utilization review programs, and other programs such as second surgical opinion programs. Studies show that the results of different programs and interventions vary both in effectiveness and longevity.

Changes in physician payment methods can also influence physicians' incentives for the use of medical technologies. Physicians who are paid on a fee-for-service basis have financial incentives to see more patients more often and provide more technologies. Physicians (or practice plans in which they participate) paid on a per capita basis have financial incentives to increase the number of their patients but to keep the number of patient visits low (or nonexistent) and to use particularly low-cost technologies. The financial incentives under a fee schedule system depend on the particular type of schedule adopted. Under fee schedules based on patient visits, physicians have incentives to schedule more visits but disincentives to use a large number of technologies (particularly those whose costs are high in relation to the fee per visit received). Under fee schedules based on episodes of illness, physicians have incentives to treat for more episodes but to keep patient visits for each episode and the use of costly technologies at a minimum.

Most changes in Medicare physician payment methods would necessitate a reformulation of the diagnostic and procedural codes for physician services that are currently used by the program. The present coding system makes it fairly easy for physicians to adopt and use medical technologies. Furthermore, the large number of procedural codes makes it fairly easy for physicians to bill for expensive services and to make expensive coding errors.

Changes in Medicare's physician payment methods that could help contain costs for the Medicare program by influencing the adoption and use of medical technologies are of two general types. One is requiring patients to assume more responsibility for their health care costs, either through increases in beneficiary cost-sharing or a reduction in the types of benefits Medicare covers. It should be noted, however, that elderly beneficiaries already have greater out-of-pocket expenses than the younger population, and increased cost-sharing may reduce their access to health care. The second type of change involves restraining the amount or changing the methods of Medicare payment to physicians (e.g., by fee schedules or freezes on current fee levels). Either approach could result in cost savings for the Medicare program, but each would have different effects on the adoption and use of medical technologies and on access to medical care by Medicare beneficiaries. Changing Medicare's claim-by-claim voluntary physician assignment policy[11] would strengthen the implementation of the other changes, although it might discourage some physicians from treating Medicare patients.

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[11] Medicare permits physicians the option of being paid directly by Medicare, called "accepting assignment," or being paid directly by the patient. If a physician does not accept assignment, the Medicare reasonable charge, which is paid directly to the patient, may be less than the physician's actual charge, and the patient is responsible for the difference between the two.

Alternative Approaches to Changing Incentives for Medical Technology Adoption and Use

Alternative approaches that could be used by Medicare to foster the appropriate adoption and use of medical technologies, and ultimately save costs, include two general policy mechanisms: 1) methods to foster competitive behavior by providers, and 2) administrative changes in Medicare. These mechanisms include changes involving the general health care system that Medicare could embrace and changes in the structure of the Medicare program itself.

It is generally believed that increases in the costs of the Medicare program and of the overall health care system can be contained by the rational adoption and use of medical technologies, which includes using technologies in appropriate settings. An important method of stimulating such adoption and use is to foster competitive behavior by providers. In most cases, it is through policies encouraging the use of alternative sites and organizations for health care delivery that competitive behavior is expected to occur. Alternatives to fee-for-service, solo physician office practices and traditional inpatient hospital settings include site alternatives, such as freestanding ambulatory surgery centers, emergency care centers, hospices, hospital outpatient departments, home health care, and nursing homes; and organizational alternatives, such as health maintenance organizations, the use of primary care gatekeepers, and preferred provider organizations.

Photo credit: National Institutes of Health

Home health care as a substitute for an extended hospital stay may be underutilized

Long-range cost containment in the Medicare program is constrained by the kinds of health care delivery systems available and the limited influence that Medicare financing can have on the settings of care and kinds of technologies provided. In recent years, the Medicare program has granted exceptions to specific alternative sites of care (e.g., freestanding ambulatory surgery centers) and encouraged the demonstration and evaluation of alternative organizations for health care delivery (e.g., preferred provider organizations). Thus, Medicare's efforts in developing competition with the types of care predominantly available have been to identify and encourage other types of provider practices and modes of delivery. In the long run, it is hoped, alternatives of these types will lead to cost-effective health care.

A complementary approach to increasing competition among providers involves moving from the current Medicare program structure to making available other types of health insurance coverage to beneficiaries. The most discussed possibility is the use of vouchers, wherein Medicare beneficiaries would receive a specified amount of money to purchase health insurance from the marketplace instead of participating in the traditional Medicare program. Important decisions regarding competition for policymakers in the Medicare program are: 1) the relative emphases to be placed on the insurance versus the alternative delivery systems approach, and 2) the pace of adopting the various competitive approaches into Medicare. To increase the capability of Medicare to embrace competitive approaches, the program could undergo an administrative change—merging Parts A and B. Merging the two parts could alleviate the financial problems of the Medicare program and improve the quality of care for patients.

POLICY OPTIONS

The final chapter of this report presents policy options for congressional consideration. Rather than to recommend specific actions, OTA's policy is to provide Congress with a series of alternative actions and discussions of the possible consequences of implementing them. The policy options in this report are organized by the following issue areas:

- How can the Medicare coverage process for specific technologies be improved?
- How can Medicare's hospital payment system incorporate appropriate incentives for generating effective and efficient adoption and use of technology?
- How can Medicare's physician payment method be used to improve incentives for appropriate technology adoption and use?
- What broad approaches, other than those directly involving Medicare's payment mechanism, could be used by Medicare to encourage the appropriate adoption and use of medical technology?

Findings and options related to each issue are presented in chapter 9.

Part One

2.

Medicare Policies Affecting Medical Technology

Life can only be understood backwards, but it must be lived forwards.

Soren Kierkegaard

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2.
Medicare Policies Affecting Medical Technology

INTRODUCTION

Because of its size and scope and because other third-party payers often follow its example, the Medicare program is a major force in the structure and performance of the U.S. health care system. Medicare currently accounts for more than 35 percent of national health spending for hospital care and more than 18 percent of national spending for physicians' services (135). Furthermore, in fiscal year 1984, program spending is expected to increase by 16.3 percent to $66.5 billion (340). Medicare's policies and procedures affect all aspects of health care delivery in the United States, including financing, administration, organization, and personnel. Medicare also affects the *content* of U.S. health care by its influence on the development and diffusion (i.e., adoption and use) of medical technology.

Despite its importance, however, the Medicare program is only one of many institutions that affects the development and diffusion of medical technology. Other institutions that affect the direction and pace of technological change include Federal agencies such as the National Institutes of Health and the Food and Drug Administration (FDA), as well as private organizations ranging from manufacturers of drugs and devices, hospitals, private insurers, and professional medical societies.[1] Some programs, such as the certificate-of-need program, have been enacted to influence medical technology but have not had the intended impact.

This chapter analyzes the extent and limits of Medicare's contribution to the development and diffusion of medical technology. It begins by describing a model of the process of technological change and then considers the effects on this process of Medicare's eligibility, benefits, and payment (including beneficiary cost-sharing) policies. The effect of medical technology on Medicare costs, another important interaction between Medicare and medical technology, will be considered in chapter 3.

DEVELOPMENT AND DIFFUSION OF MEDICAL TECHNOLOGIES[2]

Broadly defined by OTA, medical technologies are the drugs, devices, medical and surgical procedures used in medical care, and the organizational and supportive systems in which such care is provided (341). In the past few decades, numerous and impressive changes have been made in the types of medical technology available to the health care system. In the case of drugs, devices, and procedures, many new technologies, new uses of established technologies, and improvements on technologies have been developed and marketed. Furthermore, sophisticated managerial technologies, such as computer-based hospital information systems, are being purchased and used with increasing rapidity. Alternatives to the traditional modes and sites of health care delivery—the hospital and the physician's office—that have proliferated recently include a variety of alternative organizational arrangements, including hospital chains, hospital management corporations, freestanding emergency care centers, and ambulatory care centers (see ch. 8).

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[1] For an analysis of public and private sector roles in the development and diffusion of medical technology, see earlier OTA reports, including *Strategies for Medical Technology Assessment* (359) and *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice* (352), as well as *Toward Rational Technology in Medicine* by H. D. Banta, C. J. Behney, and J. S. Willems (24).

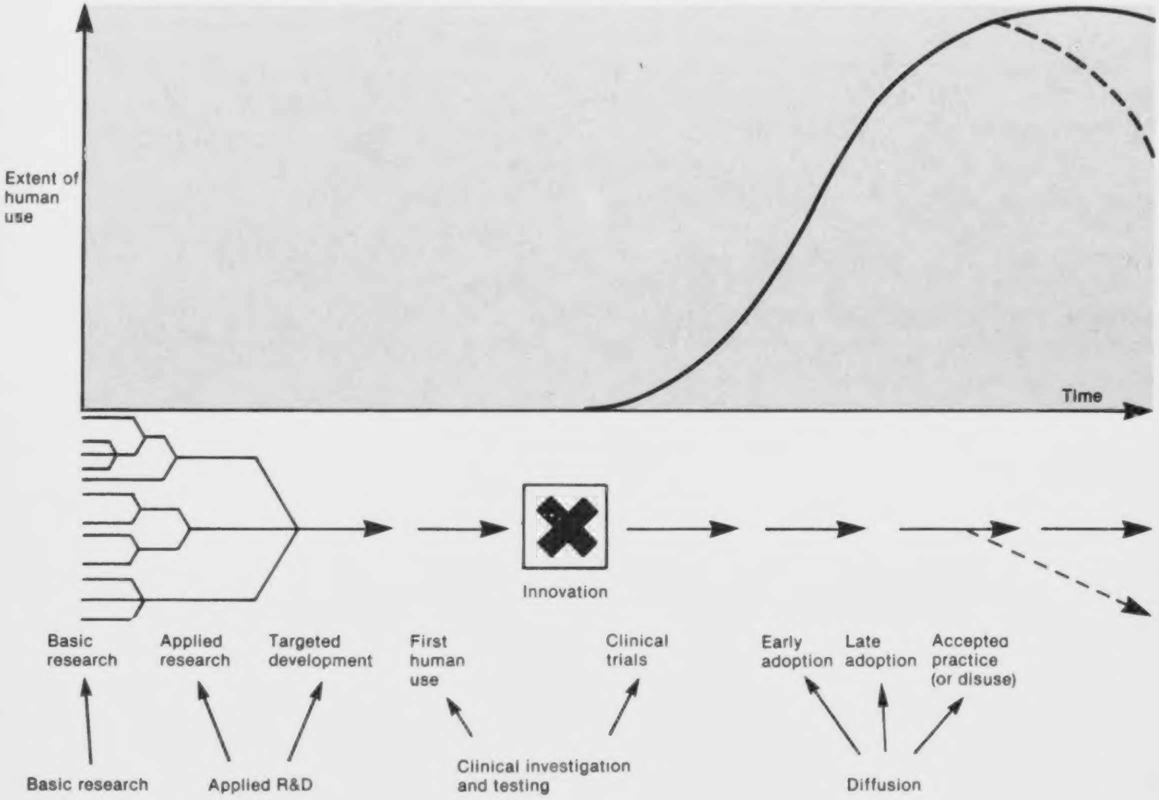
[2] The development and diffusion of medical technology are described in detail in previous OTA reports, including *Assessing the Efficacy and Safety of Medical Technologies* (341) and *The Impact of Randomized Clinical Trials on Health Policy and Medical Practice* (352).

The process of technological change occurs in two stages: the development of a technology and the subsequent diffusion of the technology into medical practice (24). This process may be divided into sequential steps within the developmental and diffusion stages for the purpose of analysis, as shown in figure 1. But the process of change is often less linear and systematic than the generalized version depicted in the figure.

The *development* of medical technology occurs in various sites and with a variety of funding sources, depending on the type of technology. While most of the basic biomedical research and some applied research and technology development in this country is funded by the Federal Government, the greatest portion of applied research and technology development is funded by private industry. Much of modern medical technology is a combination of drugs, medical devices, and human skills, and its development is very complex and not well understood.

The role of Medicare and other payment systems in the development of drugs, devices, and procedures has received little study.[3] In theory, however, payment systems can influence the development of some types of technology that are produced by the private sector. In order for a private firm to justify committing funds for the

Figure 1.—A Model for the Development and Diffusion of Medical Technologies



SOURCE: Office of Technology Assessment.

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[3] The forthcoming OTA report, *Federal Policies and the Medical Devices Industry* (345), will provide information on the role of payment systems in the development of medical devices.

research and/or development of a potential new medical device, for example, the firm must perceive the existence of a market for the innovation (345). A payment system that favors the adoption of new devices would help a firm make a decision to proceed with development. The development of technologies such as hospital information systems may be subject to market influences as well. Theoretically, Medicare's new inpatient hospital payment system mandated by the Social Security Amendments of 1983 (Public Law 98-21) should stimulate the development of new hospital information technologies. It is clear that payment systems have played an important part in the development of some new organizational patterns of medical care such as preferred provider organizations or multihospital systems (325).

The *diffusion* of a medical technology into the health care system has two phases: the initial phase in which decisions are made to adopt the technology, and a subsequent phase in which decisions are made to use the technology (24). Adoption has been studied far more by researchers than use has and has also been the subject of much greater direct involvement by the Government (24). Decisions to adopt medical technology within organizations such as hospitals are made by physicians, hospital administrators, and purchasing departments. Decisions about using technology are primarily made by physicians, although patients' decisions are also important. The use of a technology is obviously dependent on its adoption. The exact relationship between the two phases, however, has not been established.

Before *adoption* (or rejection) can occur, knowledge about a technology must be communicated to potential adopters (24). One focus of studies on the adoption of medical technology, therefore, is how knowledge about technology is communicated. Research on communication about drugs has led to the description of a two-step model. The first step is the flow of information from industry to those physicians who are opinion leaders. The second step is the transfer of information from the physician opinion leaders to their followers through informal channels (324). Recent research on the adoption of hospital information systems found a similar two-step model (16).

Another focus of studies on the adoption of medical technology is on the factors influencing adoption. Such factors include the characteristics of the technology (e.g., the complexity of understanding and using it), the characteristics of the adopter (e.g., level of training in the case of physicians, organizational structure in the case of hospitals), and characteristics of the environment (24). Third-party payment, including Medicare payment, is one of the environmental factors affecting medical technology adoption. Third-party payers pay more than 90 percent of all hospital expenditures, thus facilitating the adoption of costly hospital technologies (24).

The factors affecting the *use* of technology include physician training, increasing physician specialization, concerns about malpractice suits, industry promotion of its products, the organization of medical care, and payment for medical services (24). Unfortunately, however, the degree of their influence is not known. How physicians behave in their use of medical technologies and how payment methods and other characteristics of the health care system influence their behavior are questions addressed in chapter 7.

OVERVIEW OF MEDICARE POLICIES THAT AFFECT MEDICAL TECHNOLOGY

The principal intent of the 1965 legislation that established Medicare under Title XVIII of the Social Security Act (Public Law 89-97) was to increase elderly persons' access to medical services by removing financial barriers to such services, particularly to needed hospitalization (317). In 1965, there was less concern about the cost of the services than there was about the problems of access, primarily because there was little reason for concern. After the inception of the program, however, the costs of Medicare escalated dramatically, as did all health care costs. Thus, most of the

Medicare legislation enacted after 1965, with the exception of laws increasing the numbers and kinds of populations eligible for Medicare (see section on eligibility), has been passed with the intention of holding down Medicare's cost increases (see table 1). Efforts to control costs to date have met with little success.

One of the factors that contributes to Medicare costs and to health care costs as a whole is the adoption and use of medical technology. How the adoption and use of medical technology influences the cost of the Medicare program will be discussed in chapter 3. This chapter provides an overview of Medicare's eligibility, benefits, and payment (including beneficiary cost-sharing) policies and briefly describes the influence of each of the policies on the adoption and use of medical technology.[4]

Eligibility

To increase elderly persons' access to mainstream health care services, the Medicare law mandated eligibility for insurance benefits, including specific technologies, for most Americans 65 years and over. Eligibility was extended to disabled persons and most persons with end-stage renal disease (ESRD) on July 1, 1973, by the Social Security Amendments of 1972 (Public Law 92-603). Largely because of increases in the number of Americans who are 65 and over, the size of the Medicare population has increased substantially since the program's inception (see table 2). This trend is expected to continue.

Table 1.—Limitations Placed on Medicare Payment Levels

Public Law 92-603 (Social Security Amendments of 1972):
- Limits on hospital routine operating costs
- Use of a Medicare Economic Index in limiting rises in physician fees
- Authority for prospective reimbursement experiments
- A Professional Standards Review Organization to review medical necessity of services

Public Law 97-35 (Omnibus Reconciliation Act of 1981):
- Limitation on Part B premium increases suspended for 1 year so that premiums could be increased to comprise 25 percent of Part B costs

Public Law 97-248 (Tax Equity and Fiscal Responsibility Act of 1982):
- Per case limit on operating costs in hospitals, with potential to keep some of the savings as an incentive
- Extension of limits on hospital routine operating costs to ancillary services

Public Law 98-21 (Social Security Amendments of 1983):
- Diagnosis Related Groups (DRGs) for hospital payment

SOURCE: Office of Technology Assessment.

As of July 1, 1982, Medicare beneficiaries numbered close to 30 million people, about 12.7 percent of the U.S. population. Because of the size and characteristics of the population eligible for Medicare benefits, there is a substantial market for medical technology. By definition, Medicare enrollees are either aged or disabled and thus are disproportionately high users of health services in general and of medical technology in particular (see ch. 3). Elderly people represent 90 percent of Medicare beneficiaries (see table 2). Chronic conditions, most often conditions of middle and old age, require medical services for long periods of time (273). The elderly population visits physicians and uses hospitals and nursing homes (organizational medical technologies) much more often than the younger population (194). In 1982, for example, people aged 65 or over represented only 11 percent of the noninstitutionalized population but accounted for 29.8 percent of the hospital short-stay days of care (408). The older the elderly individual, the more health care services are provided, particularly hospitalization and skilled nursing care (328). And the proportion of older individuals in Medicare's elderly population is increasing. In 1966, 37 percent of Medicare's elderly enrollees were 75 years or older; in 1981, however, the figure was 41 percent (328).

Disabled people represent only 11 percent of Medicare enrollees (see table 2). Nevertheless, their eligibility for Medicare benefits has affected Medicare expenditures for services (328). The Congressional Budget Office estimates that in 1984, Medicare payment for a disabled person will be $2,136, while payment for an elderly enrollee will be $1,773 (328). The *patterns* of use of health care services by the disabled, however, have not been studied (328).

People with ESRD require some form of dialysis or kidney tranplants to prolong their lives. Medicare's ESRD population represents 0.26 percent of Medicare enrollees (see table 2). An estimated 93 percent of the U.S. population with ESRD is

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[4] As noted in ch. 1, "medical services" is often used interchangeably with "medical technology" in this report.

Table 2.—Number of Elderly and Disabled Beneficiaries Enrolled in Medicare by Type of Coverage, Selected Years From 1966 to 1982

Enrollment year[a]	Total number of Medicare beneficiaries	Number of elderly[b] beneficiaries	Number of disabled[c] beneficiaries	Number of elderly and disabled beneficiaries with ESRD[d]
1966	19,108,822	19,108,822	—	—
1973	23,545,363	21,814,825	1,730,538	NA[e]
1974	24,201,042	22,272,920	1,928,122	18,564
1979	27,858,742	24,947,954	2,910,788	60,608
1982	29,494,219	26,539,994	2,954,225	76,117

[a] Enrollment year begins July 1.
[b] All beneficiaries aged 65 and over, including those with end-stage renal disease.
[c] All beneficiaries under age 65, including those with end-stage renal disease.
[d] End-stage renal disease.
[e] NA—information not available.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, *1966-1979 Data Notes: Persons Enrolled for Medicare, 1979*, HCFA publication No. 03079 (Baltimore, Md.: HCFA, January 1981); and H. A. Silverman, Medicare Program Statistics Branch, Health Care Financing Administration, personal communication, August 1983.

enrolled in Medicare (195). Thus, Medicare policies can be clearly identified as a major influence on the diffusion of the technologies used in the treatment of this disease. The effects of Medicare benefits and payment policies in this area are discussed further below.

Benefits

Title XVIII of the Social Security Act specifies the broad categories of benefits for which the Medicare program will pay under the two parts: Part A, Hospital Insurance, and Part B, Supplementary Medical Insurance.[5] Part A's primary purpose is to provide insurance against the costs of inpatient hospital care. Other benefits include payment for post-hospital extended care services, home health services, and, as of April 1, 1982, inpatient alcohol detoxification services (see table 3). Part B covers medically necessary physician services, outpatient hospital services, outpatient physical therapy and speech pathology services, and various other limited ambulatory services and supplies, such as prosthetic devices and durable medical equipment (see table 3). Part B also covers home health services for those Medicare beneficiaries who have Part B coverage only. Part A is an entitlement program and is available without payment of a premium to those eligible.[6] Participation in Part B is voluntary and requires payment of a monthly premium.[7] Except for individuals who choose not to participate in Part B, premiums are deducted automatically from social security checks. In 1982, 99 percent of the elderly and 92 percent of the disabled people enrolled in Part A were also enrolled in Part B (328).

Although Medicare pays for a wide variety of services in a variety of settings, Medicare's benefit package is concentrated primarily on acute care technologies provided in institutional settings, particularly those provided as inpatient hospital services. Of Medicare's $52.2 billion in payments for 1982, $34.6 billion (66.3 percent) was for inpatient hospital services (135,151). In 1978, Medicare paid for almost 75 percent of the elderly's hospital bills; other public sources paid for almost 13 percent, and the remaining 12 percent was paid for by private health insurance (7 percent) or directly by the patient (5 percent) (124). Medicare's impact on hospital use can be seen from examining hospital discharge rates. From 1965 to 1982, the discharge rate for persons 65 years and over (i.e., Medicare beneficiaries) from acute care hospitals increased 36 percent. The discharge rates for other age groups during the same period, how-

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[5] The Medicare law specifies broad categories of services, such as hospital inpatient services, that the program will pay for or "cover." It also lists a number of specific services that it will not cover. HCFA or Medicare contractors decide the coverage status of particular technologies not mentioned in the legislation. For a full discussion of coverage policy for such specific technologies, see ch. 5.

[6] Individuals not eligible for Part A include those who work for a nonprofit organization that has chosen not to join Social Security, those who work for a foreign employer overseas, the President of the United States, and others.

[7] The Part B premium was $14.60/month as of Jan. 1, 1984, and is due to increase on Jan. 1, 1985.

Table 3.—Medicare Benefits and Limitations, as of January 1984

Kind of care	Medicare pays	Beneficiary pays	Comments
Part A			
Hospitalization	1-60 days	Initial deductible ($356)	Deductible and copayments are adjusted annually
	61-90 days	Daily copayment ($89)	
	91-150 days	Daily copayment ($178)	150 days of coverage includes a lifetime reserve of 60 days that can be used only once
	After 150 days—no coverage		
Psychiatric	Same as hospitalization	Same as hospitalization	Only 190 days of coverage, usable only once
Skilled nursing facility[a]	1-20 days	Nothing	—
	21-100 days	Daily copayment ($45)	
	After 100 days—no coverage		
Home health services[b]	Unlimited visits Reasonable costs	Nothing	Beneficiary must be eligible for Part A
Part B			
		SMI basic premium = $14.60/mo	
Home health services	Unlimited visits Reasonable costs	Nothing	Beneficiary eligible for Part B only
Physician and other medical services	80% of approved charges after deductible is met	Initial yearly deductible ($75)	—
Immunizations	Pneumococcal vaccine and those required for treatment and ordered by physician	Deductible does not apply	—
Chiropractors' services	Manual manipulation of the spine	All other costs	—
Most routine foot care	Nothing	All costs	—
Dental care	Jaw surgery and setting	All other costs	—
Dentures	Nothing	Total costs	—
Hearing and eye exams	Nothing	Total costs	—
Eyeglasses and hearing aids	Nothing	Total costs	—
Routine physical exams	Nothing	Total costs	—
Prosthetic devices	Those needed to substitute for an internal body organ, i.e., heart prostheses. Also artificial limbs and eyes, arms, legs, back, and neck braces	All other costs	—
Durable medical equipment	If rented, help with approved charges; if bought, monthly payments until Medicare's share is paid or equipment no longer necessary. If equipment is for long-term use, payment is made in a lump sum		—
Medical supplies	Dressings, splints, and casts	All other costs (i.e., common first aid supplies)	—
Blood	For all but first three pints	First three pints or replacement	—
Outpatient mental illness	$250/yr	All costs above $250/yr	—
Outpatient physical therapy or speech pathology	As treatment:		
	In doctor's office, 80% of approved charges after deductible	$75 deductible 20% coinsurance	—
	From physical therapist, $400/yr maximum	All costs above $400/yr	—
	From clinic, home health agency, or other agencies, 80% of approved charges after deductible	$75 deductible 20% coinsurance	
End-stage renal disease treatment	80% of approved charges: Hospital outpatient dialysis: $131/treatment Independent clinic dialysis: $127/treatment Home dialysis: $127/treatment	$75 deductible, 20% coinsurance	Coverage ends 12 months after the month maintenance dialysis treatment stops or 36 months after month of kidney transplant
Hospice	Prospectively per day, the following: —Routine home care ... $46.25 —Continuous home care: Total cont. care rate ... $358.67 For 8 hrs. cont. care ... 119.56 Hourly rate ... 14.94 —Inpatient respite[c] rate ... 55.33 —General inpatient care rate ... 271.00	5% of cost to program for: —Drugs and biologicals (per drug) (not to exceed $5 per prescription) —Inpatient respite care (per day) (not to exceed inpatient hospital deductible)	Beneficiary also pays Medicare deductibles and coinsurance payments, and the difference between reasonable and actual charges on unassigned claims for covered services other than hospice care. Hospice coverage consists of two 90-day periods and one 30-day period, to be taken in that order

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[a] Coverage for skilled nursing facility services was limited to only 9.1 enrollees per 1,000 in 1980 (*Medicare and Medicaid Data Book*, 1983).

[b] Coverage for home health agency services was limited to only 33.6 enrollees per 1,000 in 1980 (*Medicare and Medicaid Data Book*, 1983).

[c] Respite care is defined in the regulations as short-term (not reimbursed after 5 days) inpatient care provided to the individual only when necessary to relieve the family members or other persons caring for the individual during period of hospice election.

Data Sources:

1. U.S. Department of Health and Human Services, Health Care Financing Administration, *Your Medicare Handbook*, January 1983 edition, SSA publication No. 05-10050 (Baltimore, Md.: Social Security Administration, January 1983).
2. *Federal Register*, 48(243):56008, Dec. 16, 1983.
3. *Federal Register*, 48:21254-21291, May 11, 1983.
4. U.S. Department of Health and Human Services, Health Care Financing Administration, Division of Public Information, personal communication, Jan. 23, 1984.

SOURCE: Office of Technology Assessment.

ever, either decreased, remained the same, or increased slightly (see ch. 3).[8]

Medicare's benefit policy has favored the development of some technologies in an inpatient setting. For example, Medicare coverage emphasizes treatment for alcoholism provided in traditional acute care institutional settings, rather than that provided in the freestanding inpatient alcoholism facilities that have developed over the last 15 years or in outpatient alcoholism treatment centers. As a result, a substantial network of inpatient alcoholism treatment facilities has developed, despite evidence that outpatient treatment may be as effective and certainly is less costly (348).[9]

Since Medicare's enactment, practically all of the Nation's elderly have gained access to services provided in hospitals and to a lesser extent to services provided in ambulatory settings (81). Some analysts contend that the quality of life for Medicare beneficiaries has improved with access to inpatient hospital services such as surgical services. The frequency of certain surgical procedures that improve the functional status of the elderly, such as cataract operations and arthroplasty,[10] has increased dramatically as a result of Medicare (91,92). Furthermore, U.S. mortality rates, which had been reaching a plateau in the early 1960's, resumed their decline in the 1970's (406). From 1968 to 1977, death rates for elderly men declined at an average annual rate of 1.5 percent and for elderly women at an average annual rate of 2.3 percent (406). The decline in U.S. death rates is almost twice the decline in Canada and European rates over the same period (81). The beginning of the sharp decline in mortality rates among older people in the United States was coincident with Medicare's enactment. Some analysts have attributed the decline to improved medical care treatment (284), and more specifically, to the services available under the Medicare program (92).

At the same time that the *mortality rates* from many diseases, including heart disease and diabetes, have been falling among the elderly, however, the *prevalence* of such diseases has increased. The reason may be that improved medical treatment of acute episodes of these conditions decreases mortality rates and thereby increases the prevalence of these conditions as chronic illnesses. The prevalence of other major illnesses—atherosclerosis, cancer, emphysema, cirrhosis, osteoarthritis—has also increased among the elderly (128). Chronic conditions require long-term care more than episodic acute care. Long-term care for the elderly requires social services as well as health services. Indeed, there is a school of thought that considers medical services to have a subsidiary role in long-term care (137). Thus, the most appropriate role of Medicare, a health insurance program, with respect to chronic conditions and long-term care is a matter of debate.[11]

Medicare's benefits do not include all health-related services. Section 1862 of Title XVIII of the Social Security Act specifies that, notwithstanding other provisions of the title, "no payment may be made under part A or part B for any expenses incurred for items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Section 1862 specifically excludes Medicare coverage of many preventive services (including routine physical checkups; eyeglasses and examinations for the purpose of prescribing or fitting eyeglasses; hearing aids and examinations for hearing aids; and immunizations other than pneumococcal vaccinations, which were added as a benefit in 1981), custodial care, most cosmetic surgery and dental services (except for special cases that require hospitalization), personal comfort items, and orthopedic shoes.

In part because of funding disapprovals by Medicare and other third-party payers, assistive communication devices, used in the rehabilitation of persons disabled by severe speech impairments, are little used (351). Although Medicare covers such devices under Part A (i.e., for use only while the person is actually in the hospital) so as to enable nonvocal patients to communicate with hospital and skilled nursing facility staff (351), it does not cover these devices under Part B because of an administrative decision that the devices are not prosthetic devices needed for the functioning of a malformed body member. Not only has sales volume been lower than anticipated, but innovations in the field appear to have been held back, in part, by the lack of coverage by Medicare and other insurers (351).

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[8] This example illustrates the increase in hospital services for elderly people relative to the general population. It does not, however, demonstrate an increase in hospital services relative to outpatient care.

[9] *The Effectiveness and Costs of Alcoholism Treatment*, OTA Health Technology Case Study #22 (348), analyzes the reimbursement issues concerning the treatment of alcoholism in depth.

[10] Arthroplasty is plastic surgery of a joint or joints, or the formation of movable joints.

[11] See the forthcoming OTA report *Technology and Aging in America* (summer 1984) for a detailed discussion of long-term care, including technology and financing issues.

Clearly, many medical technologies have been developed and diffused without Medicare coverage. One example is eyeglasses and vision aids. In 1977, among those 65 years of age and older, 193 per 1,000 population purchased glasses or contact lenses or had them repaired. The major source of payment, 78.8 percent, was the family (394). Whether there would be greater adoption and utilization by the elderly of vision aids such as eyeglasses and contact lenses if the technologies were covered by Medicare is not known.

Payment

For many years, reimbursement by Medicare has been based on reasonable costs in the case of hospitals and other institutional providers and reasonable charges on a fee-for-service basis in the case of physicians and other noninstitutional suppliers of services. Under these payment methods, providers receive greater reimbursement when they use more technology, so they have little financial incentive to use technologies judiciously, with consideration of their costs and benefits. In particular, cost-based reimbursement policy has been instrumental in facilitating the acquisition by hospitals of sophisticated, capital-intensive technology (24).

In an attempt to change the financial incentives to provide hospital care, the Social Security Amendments of 1983 (Public Law 98-21) changed the basis of Medicare payment for inpatient hospital services from retrospective cost-based reimbursement to prospective payment based on Diagnosis Related Groups (DRGs).[12] The DRG prospective payment system does not apply to all hospitals or to many other segments of the health care delivery system. The system is still being implemented, and it is too early to evaluate its effects. Medicare's method of paying physicians and other noninstitutional suppliers of services on the basis of reasonable charges has changed little since Medicare was enacted.

Payment for Hospital Services

Box A describes Medicare's traditional method of payment for hospital services. The Medicare law passed in 1965 specified that Medicare pay hospitals the reasonable cost of providing services to beneficiaries. The method or methods to be used in determining reasonable cost were left to administrative decisions. Since Medicare purchased only a portion of each hospital's costs, the costs attributable to Medicare patients ("allowable costs") had to be calculated. Like Blue Cross, Medicare adopted a method that allowed hospitals considerable discretion in calculating attributable costs (104). Under Medicare's cost-based payment method applied to inpatient services, there was no financial reason for a hospital not to spend money on technology, because it was assured of reimbursement.

There have been a number of changes in the rules and guidelines in attempts to moderate Medicare's hospital expenditures, but such attempts have had only qualified success. Until 1982, the single most important innovation in the Medicare hospital reimbursement system was the 1974 implementation of "Section 223" limits (see Box A). Although the objectives of Section 223 were to moderate the rate of increase in Medicare's hospital outlays (362), the results were disappointing. The new limits affected only a few high-cost hospitals and were relatively easy to circumvent by reclassifying formerly routine services into ancillary (and therefore chargeable) items. Section 223 limits may also have encouraged the spread of intensive care unit beds (32). The limits may have encouraged hospitals to increase lengths of stay. Finally, the limits never pertained to capital costs (depreciation, interest, and in the case of for-profit hospitals, return on equity). Hospitals were paid depreciation based on actual historical expenditures and interest payments as incurred.

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[12] See discussion section for an overview and ch. 6 for a detailed discussion of Medicare's current hospital payment system and its expected effects on medical technology.

Box A.—Retrospective Cost-Based Reimbursement to Hospitals Under Medicare

Under Medicare's traditional hospital payment method, which is currently being replaced by DRG payment, hospitals are to be reimbursed the necessary costs incurred in the support of patient care facilities and activities for Medicare beneficiaries.* Each hospital is required to submit to Medicare through local contractors known as intermediaries a cost report with the *full* costs of each revenue-generating department. Allowable costs (i.e., costs Medicare will pay for) are determined by:

1. calculating a ratio of Medicare beneficiary charges to total patient charges for each ancillary department in the hospital and then applying this to total allowable charges to determine Medicare's share;
2. calculating a separate average per diem cost for general routine services and for each special care unit in the hospital; and
3. calculating Medicare costs for malpractice insurance and self insurance fund contributions and summing the calculations.

Medicare intermediaries audit the cost reports to determine whether the costs are allowable (340). In verifying whether a cost is allowable, the intermediaries employ the "prudent buyer" principle, i.e., the costs should not exceed what a prudent and cost-conscious buyer would pay for a given item or service.

In addition to operating costs, allowable costs include the depreciation cost on buildings and equipment used to render care covered by Medicare. Depreciation is based on the original cost of the building or equipment with special rules in place for assets purchased before 1966. Medicare does not require hospitals to set aside the amount allowed for depreciation to replace the depreciated asset (funding of depreciation). Other allowable costs are the interest on current and capital indebtedness, the net cost of approved educational activities, and the return on equity capital of for-profit hospitals. Bad debts, charity, and courtesy allowances for the most part are not allowable costs. Research costs that are over and above those related to usual patient care are among other categories of costs excluded from allowable costs.

The Social Security Amendments of 1972 (Public Law 92-603), among other things, imposed caps known as "Section 223 limits" on allowable inpatient operating costs in order to moderate the rate of increases in Medicare's hospital outlays. Beginning in 1974, allowable inpatient routine operating costs per patient day were capped by an amount equal to 120 percent of the mean of such costs in a similar group of hospitals. Between 1975 and 1982, the cap was gradually reduced to 108 percent of the mean cost per day in the peer group hospitals.

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*This method remains in place for those hospitals not yet under DRG payment and for excluded hospitals and hospital units.

Cost-based treatment of capital costs, which remains to this day, provides no disincentive for hospitals to adopt the capital-intensive technologies that they wish to adopt. The inclusion of depreciation cost as an allowable cost means that the cost of the equipment and buildings is passed through the hospital to the Medicare program. The treatment of capital costs by Medicare has also facilitated the ability of hospitals to borrow capital with little risk. Low-cost borrowing has made it easier for hospitals to purchase buildings and equipment than it would be if the hospitals found it necessary to generate capital for such expenditures internally. Medicare's traditional approach to capital investment is seen in another capital-related provision. Profitmaking hospitals can include a reasonable return on equity (capital invested and used in providing patient care) as an allowable cost. Thus, with limited financial constraints, it has been to some hospitals' advantage to increase their technological capability in response to demand rather than through a process of assessment of need, however defined. Until very recently, the organization of the hospital industry has also provided incentives for technology adoption.

In August 1982, Congress made some major revisions in Medicare's traditional cost-based reimbursement system for hospitals by passing the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Public Law 97-248). Among other things, TEFRA imposed a hospital-specific limit on the amount of inpatient operating costs per case that Medicare would reimburse (see Box B). Medicare's inpatient hospital payment method was changed more dramatically when the Social Security Amendments of 1983 (Public Law 98-21) mandated the phasing in over a 3-year period beginning in October 1983 of a new inpatient hospital payment method based on a national set of per case prices for patients in 470 separate DRGs (see Box B).[13] The DRG prices will apply to virtually all short-term acute-care general hospitals in the United States. Capital costs will continue to be paid as under the old system until the end of the transition period. At the time Congress passed the 1983 amendments, it contemplated, but did not specify the method for, the incorporation of payment for capital into the DRG pricing system.

Payment for Physicians' Services[14]

Except for the imposition of minor restraints on the rate of increase of physicians' upper limit payment levels, Medicare's method of paying physicians and other noninstitutional suppliers of services for charges on a fee-for-service basis has changed little since Medicare was enacted. Box C provides a description of this payment method. Most charge-based payment by Medicare—over 70 percent in 1982—is made to physicians for care provided in ambulatory and institutional settings (338).

Under Medicare's current method of payment for physician services, most of the charge for a service is passed through to the beneficiary, who, in turn, is protected from some part of the charge by Medicare.[15] This method of physician payment encourages the use of medical technology by providers, particularly if the charge-to-cost ratio is high. When payment is based on a fee paid for each service, physicians' revenues are determined to a large extent by the number and intensity of services delivered and the fee received for each service. The use of technology by fee-for-service physicians is sensitive to the additional revenue they receive (229).

Medicare's method of paying physicians also gives them an opportunity to acquire and use expensive, technically sophisticated technology in their offices. When a technology is provided as an office service, the physician's capital investment in the technology may be incorporated into the charge to the patient for the service. In 1980, 18.9 percent of the 1,471 operational computed tomography (CT) scanners, were in private offices and clinics (347). At the time, scanners were expensive. Even the so-called lower priced models of head scanners listed from $95,000 to $200,000 (347).

Although no payment method automatically provides incentives for one technology over another, any payment method can be structured to do so. The payment levels that Medicare and other third-party payers have established under the charge-based method of paying physicians provide incentives for the use of new and often expensive technologies. As noted in Box C, Medicare carriers refer to relative value systems when establishing charges for new technologies.[16] In most instances, the reimbursable charge was established at an early point in the history of the technology (52). Although later technological advances and higher rates of utilization may have substantially reduced the time, judgment, skill, and cost required to use the technology, this change is not reflected in the physicians' fee level or Medicare's reimbursement level (235). Furthermore, the payment level that Medicare has established for complex and expensive technology is

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[13] See OTA's technical memorandum entitled *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343) for further discussion of Medicare's new hospital payment system.

[14] See ch. 7 for a detailed discussion of physician payment and medical technology.

[15] The effect of Medicare's beneficiary cost-sharing policy on technology is discussed in a following section.

[16] Relative value systems establish a quantitative but nonmonetary scale on the worth of one procedure as compared to all other procedures (315). For example, if administration of a measles vaccine had a relative value of 2.2 and the conversion factor is 10, then the payer would pay the physician a maximum of $22 for the immunization.

Box B.—Prospective Per Case Payment to Hospitals Under Medicare

The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Public Law 97-248) made major revisions in Medicare's retrospective cost-based hospital reimbursement system. In addition to extending the existing "Section 223 limits" (see Box A) to include ancillary and special care unit operating costs, TEFRA imposed a hospital-specific maximum limit on the amount of inpatient operating costs per case that would be reimbursed. The new approach, which became effective in October 1982, has two key elements: 1) the limit is determined either by the hospital's own per case cost in a previous year or the average per case cost of similar hospitals; and 2) the hospital stands to gain a small portion of per case savings it can generate. TEFRA put no limit on capital costs (depreciation and interest), direct teaching expenses, or outpatient services. These remained "pass-through" items, i.e., items not subject to the new system's controls.

A more sweeping revision of Medicare's hospital payment system was signed into law in April 1983. The Social Security Amendments of 1983 (Public Law 98-21) mandated the phasing in over a 3-year period of a prospective payment system for inpatient hospital services. Payment is to be based on a national set of per case prices for patients in 470 Diagnosis Related Groups (DRGs). DRGs are a set of patient classes developed to reflect differences in resource needs among different kinds of patients. Several types of hospitals (psychiatric, long-term, children's, and rehabilitation hospitals) and hospital units (psychiatric and rehabilitation units operating as distinct parts of acute care hospitals) are excluded from the prospective payment system and will continue to be reimbursed on the basis of reasonable costs. Capital costs and the costs of direct medical education remain pass-through items.

Under the DRG system, Medicare payment is made at a predetermined, specific rate for each discharge. During the 3-year transition period, which began in October 1983, a declining portion of the total prospective rate is to be based on hospital's historical costs in a given base year, and a gradually increasing portion is to be based on a blend of federally determined regional and national rates. Beginning in the fourth year, Medicare payment for inpatient care will be based on a set of national DRG rates. The price for a DRG will be adjusted for the hospital's urban or rural location and area wage rate. For 1984 and 1985, the prospective payment system must be "budget neutral," i.e., payments may not be greater than nor less than the payments that would have been paid under TEFRA.

The DRG prospective payment system applies to all inpatient discharges from short-term acute care general hospitals in the United States except for a small number of cases (set by statute as 6 percent of the total) with unusually long lengths of stay or high charges. The rate of payment for these "outlier" cases will be increased by the estimated cost of care during the extended stay.

The initial set of DRG prices is based on the 1981 average inpatient operating cost per case for each DRG in a 20-percent sample of Medicare claims. The law requires that the DRG prices be updated regularly in two ways. First, an overall annual rate of increase is applied to all DRGs to keep pace with the general level of inflation and rate of technological change in the economy. Second, the relative weights (i.e., the ratio of one weight to another) must be assessed and recalibrated at least once every 4 years, with the first recalibration scheduled for October 1985. The recalibration must reflect changes in treatment patterns, technology, and other factors that alter the relative use of hospital resources among DRGs. A Prospective Payment Assessment Commission established by the law is responsible for making recommendations regarding the annual payment increase and recalibration and for evaluating any such adjustments made by the Secretary of the Department of Health and Human Services.

Public Law 98-21 requires the Medicare program to participate in any State-legislated alternative prospective payment program that: covers at least 75 percent of the State's population; makes provisions for competitive health plans; assures the Federal Government that access to hospital care for Medicare and Medicaid beneficiaries will not decline; and assures the Federal Government that hospital costs will not be higher under the State program. Thus, it encourages States to experiment with hospital payment systems that cover third-party payers in addition to Medicare and differ from DRG payment.

Box C.—Charge-Based Reimbursement to Physicians Under Medicare

Title XVIII of the Social Security Act specifies that payments for physician services under Part B of Medicare are to be made on the basis of reasonable charges. The criteria for determining reasonable charges are described in both statute and regulations. The criteria are applied by Medicare contractors known as carriers in determining the reasonable charge for each service provided in the absence of unusual medical complications or certain other circumstances.

Medicare carriers maintain records of the services provided and the charges billed by physicians in an area. Then they develop individual and areawide statistical profiles of physician charges. The reasonable charge is the lowest of a physician's actual charge, a physician's customary charge, or the area's prevailing charge. The actual charge is a physician's billed charge for the service provided. The customary charge is the median of the charges filed by a physician during the previous year for the service. Until 1976, the prevailing charge was the 75th percentile of the distribution of customary charges of all area physicians the previous calendar year, weighted by the number of times each physician billed for the service.

The calculation of prevailing charges was changed by the Social Security Amendments of 1972 (Public Law 92-603), which placed limitations on the yearly increases in prevailing charge levels beginning in 1976. The amendments established a Medicare Economic Index that limits the rate of increase in physicians' fees to the rate of increase in their costs. Prevailing charges are now calculated by multiplying the 1973 prevailing charges by the current index (35). The index is promulgated annually for the 12-month period beginning July 1.

Prevailing charges vary widely from community to community, and in some areas, different payment levels are calculated and applied to general practitioners and specialists.

When there is no reliable statistical base for determining a physician's customary charge or the prevailing charge for a medical procedure in the area, Medicare carriers may use a relative value system (235). Medicare carriers refer to relative value systems when establishing charges for new procedures, since the systems describe and code particular physician services.

Medicare permits physicians the option of being paid directly by Medicare, called "accepting assignment," or being paid directly by the patient. Assignment is accepted on a bill-by-bill basis. If a physician accepts assignment, he or she bills the program directly and is paid Medicare's reasonable charge. If a physician does not accept assignment, the Medicare reasonable charge, which is paid directly to the patient, may be lower than the physician's actual charge, and the beneficiary is responsible for any difference between the two. In all cases, the beneficiary is responsible for 20 percent coinsurance on the reasonable charge (see Box D). The assignment rate has declined from a high of 61.5 percent in 1969, leveling off at about 50 percent (118).

usually disproportionately high. Relative value scales place higher values on "technology-oriented" procedures and devices than on other services, such as cognitive procedures and office visits (235).

Payment for Treatment of End-Stage Renal Disease

The Social Security Amendments of 1972 mandated payment under Medicare's ESRD program for both hemodialysis and kidney transplantation. Before the ESRD program was established in 1973, there were few freestanding dialysis centers, and most hemodialysis was performed in hospitals or in patients' homes. The original Medicare regulations pertaining to ESRD included financial disincentives for home dialysis as compared to facility dialysis.[17] By 1977, there were 895 approved

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[17] For example, out-of-pocket costs were required for home dialysis supplies and equipment, and reimbursement was not provided for the services of a home dialysis assistant nor for renting equipment, ordering supplies, and other bookkeeping requirements. Home dialysis patients also incurred out-of-pocket costs for home modification and higher electric and water bills.

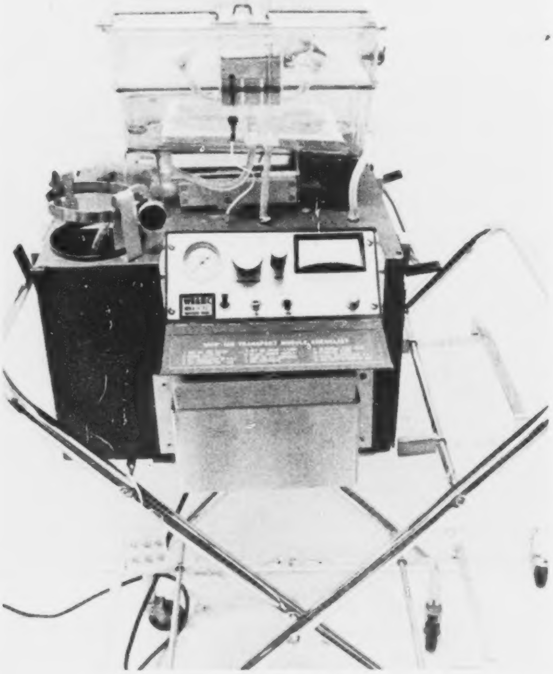

Photo credit: National Kidney Foundation, Washington, D.C.

Payment and coverage policies for end-stage renal disease technologies have fostered their use

dialysis centers in the ESRD program (262), and the percentage of patients on home dialysis had decreased significantly (see table 4). Some of the decrease in home dialysis may have been due to the stresses on family life, which led patients to use facility dialysis when Medicare coverage became available. Other factors contributing to the increased use of facility dialysis included the personal philosophy of the physician or hospital treating the patient, increased age and morbidity of dialysis patients that reduced their suitability for home dialysis, and the for-profit status of a significant percentage of dialysis facilities.

The number of patients receiving kidney transplants increased strikingly in 1973 (see table 4). After 1973, the number grew at a slower pace and then plateaued between 1977 and 1978 because of the lack of improvement in graft success rates, a decreased donor pool, and financial disincentives for undergoing transplantation that were in the Medicare regulations. When the financial disincentives, including termination of benefits the 12th month after transplant surgery, were removed in 1978, the number of transplants started to increase (359).

Escalating costs of Medicare's ESRD program were addressed in two revisions to the original

Table 4.—ESRD Patient Population, 1972 to 1982

Year	Number of kidney transplants[a]	Number of hemodialysis patients	Percentage of patients on home dialysis[a]
1972	1,993 (2,852)	10,000	40%
1973	3,017	11,000	35.9
1974	3,190	18,875	32.7
1975	3,730	22,000	28
1976	3,504	30,131	23.7 (13)
1977	3,973	32,435	11.6 (20)
1978	3,949	36,463	12.4
1979	4,271	45,565	13.0 (10)
1980	4,697	50,000	NA[b]
1981	4,885	NA	
1982	5,358	NA	

[a] Numbers in parenthesis reflect conflicting reports in the literature.
[b] NA—information not available.

SOURCE: Office of Technology Assessment, *Strategies for Medical Technology Assessment*, OTA-H-181 (Washington, D.C.: U.S. Government Printing Office, September 1982); and National Kidney Foundation, Washington, D.C., personal communication, Feb. 9, 1984.

law. The End-Stage Renal Disease Program Amendments of 1978 (Public Law 95-292) established a prospective reimbursement method to encourage efficiency and cost effectiveness. To encourage home dialysis by eliminating the 20-percent coinsurance requirement and to avoid high equipment rental payments, one of the provisions provided for reimbursement by Medicare of the full costs (100 percent) of home dialysis equipment, installation, maintenance, and repair.

The Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) discontinued 100-percent reimbursement for home dialysis equipment but called for further changes to promote home dialysis. Under regulations implementing the law, each dialysis facility receives a certain payment rate per treatment, adjusted for geographic wage differences, regardless of whether the treatment is furnished in the facility or supervised in the patient's home. Dialysis facilities have to accept the prospective payment rate as payment in full. Physicians receive a monthly capitation payment that is equal for home dialysis and facility dialysis (111).

Financial incentives favoring one dialysis location over another are related to the difference between reimbursement rates and unit costs. The difference between reimbursement rates and unit costs creates strong disincentives for performing hemodialysis in hospital dialysis centers, moderate incentives to perform hemodialysis in independent centers, and very strong incentives for home dialysis supervised by either hospital or independent centers. The strong incentive for home hemodialysis could be moderated somewhat if unit costs rise as a result of the need for more home health aides for sicker patients or those without much family support.

Average physician capitation fees under the 1983 composite rate formula will increase from $1,848 per year to $2,208 per year (+ 19 percent) for home dialysis, and decrease from $2,640 per year to $2,208 per year (− 16 percent) for center dialysis. Thus, changes in capitation rates for physician supervision of dialysis also heavily favor home dialysis over center dialysis (344).

Beneficiary Cost-Sharing

"In one sense . . . Medicare can be said to have been designed to increase utilization" (318). Yet cost-sharing provisions were included in the original Medicare legislation as a possible moderating influence on the unnecessary utilization of services (322). Box D describes the beneficiary cost-sharing provisions of the Medicare program.

The premise behind deductibles, copayments, and coinsurance is that price deters patients from seeking care and thereby lessens the use of unnecessary services. Furthermore, once beneficiaries decide to seek care, price is considered to influence patients and providers to choose less expensive technologies.

Premium payments, another form of cost-sharing, are not considered an obstacle to the use of services (28,253). Premium cost is too far removed from the use of a technology to affect patients' or physicians' behavior at the time of its use.

A number of studies of populations not in the Medicare program suggest that cost-sharing restrains the use of medical services (30,138,244, 245,246,255,259,260,261,299).[18] When beneficiaries must immediately pay for part of the cost of additional services, they choose to use fewer services than when fully insured. Low-income groups, in particular, are deterred from using services as a result of cost-sharing (30,299).

Early results of a large, well-designed and executed study—the Rand National Health Insurance Study (247)—substantiate the above findings. Individuals enrolled in health insurance plans with high coinsurance rates (50 or 95 percent, similar to income-related catastrophic coverage) were less likely than individuals enrolled in plans with no coinsurance or a low coinsurance rate (25 percent) to visit a physician and to be admitted to a hospital. Individuals in plans with higher co-

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[18] For a general discussion of cost-sharing and the adoption and use of medical technology, see the OTA assessment *Medical Technology Under Proposals To Increase Competition in Health Care* (355).

Box D.—Beneficiary Cost-Sharing Under Medicare

Beneficiaries' expenses in the Medicare program consist of deductibles and copayments under Part A (Hospital Insurance) and premium payments, deductibles, and coinsurance under Part B (Supplementary Medical Insurance). Those over 65 who are not automatically entitled to Medicare (e.g., those who work for a nonprofit organization that has chosen not to join Social Security) can participate by monthly payments of the actuarial cost of coverage.

Part A deductibles and copayments are calculated on the basis of a benefit period (a benefit period begins when a beneficiary enters a hospital and ends when the beneficiary has been out of a hospital or skilled nursing facility for 60 days in a row). During each benefit period, Part A will pay for 90 days of inpatient hospital care of which the beneficiary has to pay the first $356. After 60 days of inpatient hospital care, the beneficiary is required to pay a daily copayment of $89 until the 90th day of care. If more than 90 days of care are required in any one benefit period, the beneficiary can draw upon a lifetime reserve of 60 days that requires a copayment of $178 per day. Part A also requires a beneficiary copayment of $45 per day for the 21st through 100th day in a skilled nursing facility.

Under Part B, the beneficiary is responsible for the first $75 of approved charges in a calendar year and coinsurance of 20 percent for the remainder of approved charges. If a physician does not accept assignment (agree to accept the level of reimbursement calculated by Medicare in exchange for direct payment of Medicare's 80-percent share), the beneficiary is financially responsible for the difference between the charge billed by the physician and the allowable charge determined by Medicare.

In 1966, premiums contributed half of Part B revenues, while general revenues subsidized the other half. Subsequent legislation limited increases in the premiums to no more than the percentage increase in Social Security cash benefits. By 1978, the percent contribution of premiums to meet Part B program costs had fallen to below 25 percent (134).

The Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35) and the Social Security Amendments of 1983 (Public Law 98-21) suspended the limitation on Part B basic premium increases for the period between July 1, 1983 and January 1, 1984. During this period, premiums increased so that they represent 25 percent of program costs. Premiums rose from $13.50/month on July 1, 1983, to $14.60/month on January 1, 1984.

insurance rates also had a lower number of physician visits. There was no significant difference in hospital spending per hospital admission.

Applying results of available studies of cost-sharing on different age and sex groups to the Medicare beneficiaries may not be appropriate. There is evidence that the influence of cost-sharing on hospital use is sensitive to the age and sex of the patient (243). There are crucial differences in health status and health practices between the Medicare population and others. Not surprisingly, even before Medicare was enacted, the elderly used hospitals more than others. For example, from July 1962 to June 1964, those 65 years and older represented 9 percent of the population, but used over 25 percent of hospital days (318).

Little empirical evidence is available on the effects of deductibles, copayments, and coinsurance specifically in the Medicare program on the adoption and use of technology. However, a study of the use of supplementary health insurance by Medicare beneficiaries provides some insight into how Medicare's cost-sharing policy has affected the adoption and use of technology (199). Public and private supplementary (Medigap) health insurance is used extensively by Medicare beneficiaries. In 1976, 63 percent of aged Medicare beneficiaries had some form of private supplementary health insurance and 14 percent had public supplementary coverage, primarily from Medicaid (6 percent had both public and private supplementation). Only 29 percent had no supplementary insurance.

The study found that supplementary insurance increased the use of both hospital and physician services by elderly Medicare beneficiaries (197). Supplementary health insurance greatly increased the use of inpatient hospital services by elderly Medicare beneficiaries with or without chronic health problems. Most of the gains in utilization of hospital services came from the admission of more people into hospitals rather than from increases in length of stay. The investigators suggest that the "Part A deductible (approximately equal to the average charge for an inpatient hospital day) represents a significant barrier to the utilization of hospital services by the elderly" (199).

The effect of cost-sharing under Part B of Medicare on the use of physicians' services depended on whether the elderly Medicare beneficiary did or did not have a chronic health problem (approximately 78 percent of the elderly Medicare population have a chronic health problem). Part B cost-sharing provisions did not deter individuals with chronic health problems from seeking health care from physicians (199). On the other hand, the Part B deductible and coinsurance provisions had a decided effect on the use of physicians' services by elderly Medicare beneficiaries without chronic conditions.

Thus, it appears that cost-sharing under Medicare "leads to significantly lower levels of hospital and physician utilization than would have prevailed in the absence of the program's deductibles and coinsurance" by some members of the elderly Medicare population (199). The more fundamental question of whether cost-sharing affects the use of necessary services by the elderly requires health status data. A recent Rand study of nearly 4,000 people found that there were only small differences at the end of the study between the health status of those people with "free care" (no cost-sharing) and people who were required to pay a portion of their medical bill (various levels of cost-sharing were aggregated for the analysis) (49). However, the study population was limited to individuals between the ages of 14 and 61 without any disability, making the applicability of its findings to Medicare beneficiaries questionable (270).

DISCUSSION

Medicare policies—payment policies, in particular—have influenced the adoption and use of some medical technologies. Cost-based hospital reimbursement, with pass-through for capital expenditures, has not discouraged hospitals from purchasing new technologies. Payment for physician services and technologies at hospitals and other health care delivery sites provided financial incentives for their use without careful consideration of their impacts on costs.

Medicare payment policies generally have assured hospitals that they would be paid for the cost of new technologies. This assurance has had a direct effect on hospitals' decisions to *adopt* new technologies. Russell found that adoption of cobalt therapy, for example, was influenced by Medicare (289). In addition, since hospitals have fewer nonpaying patients since the inception of Medicare and Medicaid, they are not losing as much money to bad debt, so they are better risks for loans. Thus, the presence of Medicare patients also has an indirect effect on hospitals' decision-making regarding adoption of medical technologies.

The *use* of medical technologies is largely the responsibility of physicians. Under Medicare policies of retrospective, charge-based reimbursement, physicians have had no financial constraints on the number of such technologies provided. Instead, they have known that the hospital gained revenue for each test or procedure. Medicare's coverage policy excludes payment for items that are "not reasonable and necessary" for diagnosis, treatment, or improved functioning of a malformed body member. This has allowed physicians much flexibility in their medical technology use (see chs. 5 and 7). Under the new Medicare DRG prospective hospital payment system, with its incentives to reduce ancillary services, hospital administrators will have to work more closely with physicians regarding use of technologies.

It is important to remember that physicians have always been important actors in both the adoption and use of medical technologies. In addition to purchasing new technologies for their office practices, physicians are often the ones who suggest the purchase of new technologies to hospital administrators or boards of trustees. In their decisions, the administrators or boards may consider the importance of the individual physicians in admitting patients and the various specialties competing for the technologies, as well as the cost of the new equipment and its benefits to patients. They also may consider the extent to which the physicians use the technologies already available.

The DRG hospital payment system may change the impact of Medicare on technology. Use of hospitalization and tests and procedures during hospital stays are constrained under the new system. Efforts to control costs during hospitalizations may extend to the adoption of technologies that will lower hospital costs per case. More technologies may be moved out of inpatient settings to ambulatory settings, where Medicare payment has not yet changed. Such movement depends on the development of specific technologies, also (e.g., those used in freestanding ambulatory surgery centers—see ch. 8).

Thus, the Medicare program has influenced technology adoption and use. Yet, the strength of this influence has been limited by the fact that it is only one payer among several. Where Medicare beneficiaries make up a large portion of the patient population, such as in hospitals, Medicare policies have more impact. Medicare's influence with physicians—because physicians are the strongest factor in technology adoption and use decisions—needs to be strengthened in order to contain program costs and to rationalize technology decisions.

3.

The Impact of Medical Technology on Medicare Costs

There is no gathering the rose without being pricked by the thorn.
Bidpai

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3.

The Impact of Medical Technology on Medicare Costs

INTRODUCTION

Changes in the kinds of medical technologies[1] available and changes in the patterns of use of technologies already available continually influence health care and Medicare costs—at times moderating cost increases and at times exacerbating them. As noted in the previous chapter, various factors affect the adoption and use of medical technology. This chapter examines the patterns of medical technology use experienced by the Medicare population compared to the general population. Its primary purpose, however, is to explore the nature and size of medical technology's contribution to health care and Medicare costs.

How medical technology contributes to health care and Medicare costs is a question that can be addressed either from an aggregate perspective or from the standpoint of particular technologies or classes of technology.

The question from the aggregate perspective is whether changes in medical technology use as a whole have raised or reduced health care or Medicare costs and, if so, by how much. This perspective is useful, because it puts technology's relationship to costs into a policy perspective. Changes in the use of medical technology reflect changes in the behavior of medical decisionmakers. Quantitative estimates of technology's aggregate contribution to health care costs, therefore, reflect the importance of changes in medical decisions, which can be presumed to be influenced by policy, relative to changes in other, less controllable factors such as population growth or general wage and price inflation.

The aggregate approach is limited, however, because it ignores the patient benefits associated with cost increases or decreases, it does not take into account the underlying reasons for changes in medical decisions or practices, and it does not show that cost-saving or cost-raising changes in technology are not scattered evenly across illnesses. In short, it offers no way of knowing whether any particular technology-related rate of change in health care or Medicare costs is too high or too low.

Analyzing how specific technologies or classes of technology affect health care or Medicare costs can be more enlightening, particularly when the information that results is combined with data on efficacy and patterns of adoption and use. Analyses of the cost implications for Medicare of seven specific medical technologies are provided in this chapter.

MEDICARE BENEFICIARIES' USE OF MEDICAL TECHNOLOGY

By definition, Medicare enrollees are either aged or disabled. Furthermore, they are disproportionately high users of health care services in general and of medical technology in particular (126). Although a high proportion of health care expenditures for the elderly is for nursing homes and other long-term care services, it is important to recognize that the elderly are high users of services provided in hospitals, where medical technology is concentrated. Age-specific hospital discharge rates for selected years from 1973 to 1982 are shown in table 5. Not only has the number

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[1] As noted in ch. 1, OTA defines medical technology as "the drugs, devices, and surgical and medical procedures used in medical care, and the organizational and supportive systems within which such care is provided." The term "medical services" is often used interchangeably with "medical technology" in this report.

Table 5.—Discharges From and Days of Care in Short-Stay Non-Federal Inpatient Hospitals by Patient Age, Selected Years From 1973 to 1982

Age	Discharges per 1,000 population							Average annual percent change	Percent change 1973 to 1982
	1973	1975	1978	1979	1980	1981	1982		
< 15	70.8	71.5	68.8	70.8	71.8	72.9	71.2	0.1%	0.6%
15-44	154.4	155.4	155.1	151.8	151.3	148.7	145.0	−0.6	−6.0
45-64	182.3	194.7	193.1	192.4	196.0	195.3	195.5	0.7	7.2
≥65	341.8	359.3	381.9	361.5	405.2	396.5	398.8	1.5	16.7
All ages	154.0	158.8	159.8	156.9	161.9	160.2	167.9	0.9	9.0

Age	Days of care per 1,000 population				Percent change 1973 to 1980
	1973	1978	1979	1980	
< 15	321.9	304.8	314.7	316.4	−1.7%
15-44	878.5	824.7	817.8	793.1	−9.7
45-64	1,661.0	1,638.7	1,604.3	1,607.0	−1.0
≥65	4,136.4	4,183.8	4,182.5	4,327.5	4.6
All ages	1,192.3	1,165.4	1,158.2	1,163.0	−2.5

Data sources:

1. 1973 and 1978 data, U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1980*, DHHS publication No. (PHS) 81-1232 (Hyattsville, Md.: DHHS, December 1980).
2. 1975 and 1980 data, U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1982*, DHHS publication No. (PHS) 83-1232 (Hyattsville, Md.: DHHS, December 1982).
3. 1979 and 1981 discharge data, U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1983*, DHHS publication No. (PHS) 84-1232 (Hyattsville, Md.: DHHS, December 1983).
4. 1979 days of care data, U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1981*, DHHS publication No. (PHS) 82-1232 (Hyattsville, Md.: DHHS, December 1981).
5. 1982 discharge data, U.S. Department of Health and Human Services, National Center for Health Statistics, "1982 Summary: National Hospital Discharge Survey," No. 95, DHHS publication No. (PHS) 84-1250 (Hyattsville, Md.: DHHS, Dec. 27, 1983).

SOURCE: Office of Technology Assessment.

of discharges per 1,000 population increased dramatically for the elderly population, but in the period from 1977 to 1982, the number increased more rapidly for the elderly than for other segments of the population. Furthermore, once in the hospital, elderly people experience longer lengths of stay than do younger people.[2] It is interesting to note, however, that the covered days of care for the Medicare population increased only 4.6 percent between 1973 and 1980.

In the hospital, elderly patients use many medical technologies more frequently than the rest of the population. Table 6 presents age-specific data on surgical operations in short-stay hospitals between 1973 and 1980. In 1980, the rate of surgery among the elderly was 61 percent higher than the rate in the population as a whole. Furthermore, from 1973 to 1980, it increased by 37 percent, while the rate for the population as a whole increased only 22 percent (5).

Intensive care units (ICUs) typically represent the confluence of medical technology and intensive nursing care in a complex system of care for the critically ill. In 1980, about 18 percent of Medicare hospital stays involved intensive or coronary

Table 6.—Operative Procedures in Short-Stay Hospitals by Patient Age, 1973-80 (rate per 1,000 population)

Age	1973	1974	1975	1976	1977	1978	1979	1980
< 15	41.9	42.2	40.5	41.0	41.0	37.6	37.2	36.0
15-44	96.4	99.8	101.5	99.5	104.7	100.6	125.7	121.3
45-64	113.2	117.3	123.3	122.5	124.6	119.0	121.3	122.8
≥65	140.7	145.9	154.8	154.9	165.9	172.2	183.4	193.2
All ages[a]	89.5	92.9	95.4	95.4	99.7	97.0	110.5	109.9

[a] Because of rounding, the sum of procedures for all ages may not total.

SOURCE: I. N. Haug and R. Seeger (eds.), *Socio-Economic Factbook for Surgery, 1982*, Surgical Practice Department, American College of Surgery, 1982.

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[2] The longer lengths of stay experienced by the elderly are due in part to the use of the hospital as a substitute for nursing homes. "Backed-up" hospital patients awaiting nursing home placement have been estimated to account for 10 percent of the annual occupancy of some hospitals (371) and in 1980 cost Medicare $1.5 billion in hospital expenditures (371).

care units (161). The available evidence seems to indicate that the representation of the elderly is the same or only slightly greater in ICUs than it is in the hospital as a whole (354). Thus, while the elderly are likely to require more intensive care than other segments of the general population, once in the hospital they appear to be placed in ICUs no more often than the nonelderly population (354). Once in an ICU, however, elderly patients generally receive more interventions than other patients (57). According to Knaus, the key factor influencing the use of resources once a patient is in an ICU is acute and chronic health status, not age in and of itself (190). Elderly patients in ICUs are simply sicker than other ICU patients.

The more frequent and intensive use of specific medical technologies by elderly patients translates into a greater representation of the elderly among high-cost patients within the hospital. Thus, for example, a 1976 study of almost 27,000 patients in three short-term hospitals found that 23.8 percent of the patients were over 65 years of age, but 41 percent of the high-cost patients[3] were over 65 (437). Furthermore, the National Medical Care Expenditures Survey conducted in 1977 found that the mean charge per hospital admission was $2,198 for patients 65 or older compared to $1,251 for the nonelderly population, a difference of $947 (395). The difference reflects not only the greater use of specific medical technologies by the elderly but also the longer inpatient stays generally experienced by the elderly (10.3 days per admission compared to 7.1 days in the general population in 1977) (395). In 1977, the average daily rate for a semiprivate room was approximately $91 (180). Thus, of the $947 extra charge per stay, about $503 can be attributed to the extra use of ancillary technologies by the elderly and the rest to the longer length of stay.

The general pattern of high use of medical technology by the elderly extends beyond the hospital to ambulatory care settings as well. As shown in table 7, the rate of ambulatory visits to physicians for diagnostic services is higher among elderly persons than among other segments of the population. Interestingly, however, the rate of X-ray testing in patients who do visit a physician for diagnostic reasons is not higher in the elderly. The elderly are also relatively high users of prescription drugs, despite the fact that Medicare does not pay for outpatient prescription drugs. In 1977, about 75 percent of the population 65 or older had at least one prescription compared to 58 percent of the general population (398). Furthermore, during the decade preceding that year, the intensity of use of prescriptions by Medicare Part B beneficiaries had increased (147). Finally, the use of medical equipment and supplies outside of hospitals and nursing homes was more than twice as frequent in the elderly as in the general population (397).

It is hardly startling that elderly people use more health care services and medical technologies in the aggregate and use them more intensively than the rest of the population. The importance of this fact lies in its implications for the Medicare program. Changes in types of medical technologies available or the patterns and conditions of the use of such technologies are likely in the aggregate to have strong effects on the costs of the Medicare program precisely because of the intensity with which Medicare enrollees use technology. The next section attempts to explore the extent of that impact.

MEDICAL TECHNOLOGY'S AGGREGATE IMPACT ON MEDICARE COSTS

In order to investigate the aggregate contribution of changes in medical technology (i.e., changes in the kinds of technologies available and in the ways in which technologies are used in the practice of medicine) to Medicare costs, one must first examine the impact of technology on over-

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[3] High-cost patients were defined in the study as patients whose total charges fell in the upper 20 percent of charges for patients in the hospital.

Table 7.—Use of Ambulatory Physician Visits With Specified Diagnostic Services by Age, 1977

Age	Total population (in thousands)	*Annual number of visits per 1,000 population*			Percent of persons with at least one visit		
		Visits with any diagnostic services	Visits with X-ray	Visits with laboratory tests	Visits with any diagnostic service	Visits with X-rays	Visits with laboratory tests
<6 years	18,216	746	119	528	39.1	7.9	30.9
6 to 18 years	50,647	652	204	355	34.1	12.7	21.7
19 to 24 years	22,299	1,211	231	654	46.9	13.4	26.5
25 to 54 years	78,472	1,327	262	565	51.5	16.0	24.4
55 to 64 years	20,180	1,614	307	673	55.4	18.1	27.0
≥65 years	28,284	1,881	254	971	56.0	15.9	34.0
All ages	212,098	1,189	236	574	46.6	14.4	25.8

SOURCE: L. F. Rossiter and C. M. Horgan, "Unequal Financial Incentives for Diagnostic and Preventive Health Care," [illegible] prepared for 109th Annual Meeting of the American Public Health Association, Medical Care Section, Los Angeles, Calif., November 1981.

all health care expenditures. There are several methods for measuring technology's contribution to health care costs. The most common method is the "intensity of care" approach.

The "Intensity of Care" Approach to Measuring Technology's Contribution to Health Costs

The intensity of care approach involves dividing a change in total expenditures for health care[4] into its constituent parts:

- population or enrollment changes,
- overall wage and price inflation,
- wage and price inflation in medical care in excess of general inflation, and
- changes in "service intensity."

Changes in technology use are included in the latter two measures, although these measures also reflect other factors.

Service intensity refers to the quantity of inputs that go into producing a given unit of health care. Such inputs include labor, supplies, materials, and equipment. Labor intensity refers to the quantity of personnel used to produce a unit of health care. Nonlabor intensity refers to the quantity of materials and supplies as well as the capital plant and equipment used in producing the unit of health care.

Although changes in service intensity have been labeled the "technology factor" (132), service intensity is not synonymous with medical technology use. To understand both the usefulness and limitations of estimates of changes in service intensity, it is helpful to consider how measures of intensity are related to the changes in medical technology whose effects are desirable to identify.

One way to relate service intensity to the use of technology is to examine how hypothetical changes in medical technology would be likely to alter the operations, and thus costs, of health care institutions. The introduction of a new device in a hospital, for example, often involves both capital (nonlabor) and some operating (both labor and nonlabor) costs for its application and maintenance. If the device is more sophisticated than the average technology in the hospital, it may require more highly trained technicians, thus driving up the average wages of hospital personnel. But the services provided by the device might substitute for other services, thereby reducing labor and nonlabor costs in other areas. Or the new device may have negligible effects on hospital operations and simply be a product improvement, with a concomitant increase in product price.[5] Finally, a new device may draw into the hospital patients who would otherwise not be hospitalized, thereby increasing admissions and the routine (labor and nonlabor) costs associated with a hospital stay as well as the costs of the service itself. Of course, these admissions might reduce the costs of other sectors of health care, such as ambulatory care or drugs.

These observations suggest that the effects of changes in medical technology on health care costs must be traced through the changes' specific effects on hospital costs and other components of health care costs. Changes in hospital costs due to technological change are reflected in two measures:

- service intensity, or the quantity of inputs per admission and the frequency of hospital admissions; and
- the technical sophistication of inputs as reflected in changes in the input prices (or wages) relative to general price level changes.

Thus, changes in technology affect service intensity, but they also affect another component of hospital cost.

Each of these components of hospital cost is also affected by forces unrelated to technology. For example, both the quantity of labor used in the hospital and the average wage paid to hospital personnel may be driven up because hospitals have inadequate incentives to be efficient or because the hospital work force has been recently unionized (131). The price and quantity of medical equipment, materials, and supplies might also increase relative to general inflation because of inadequate incentives for efficiency in the hospital sector. Finally, hospital admissions are altered by changes in the incidence of illness and the general aging of the population, among other things. Thus, the components of hospital cost likely to be affected by changes in medical technology are also likely to be influenced by other factors.

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[4] This approach may also be used for one or more of the major components of health care costs.

[5] A new fully programmable cardiac pacemaker, for example, would be more expensive than more traditional pacemakers, but it would have little effect on the hospital's costs of pacemaker insertion; the full effect on hospital cost would be the increased price of the pacemaker reflecting its enhanced capabilities.

It appears, then, that **the separation of health care cost increases into their components provides at best an oblique view of the contribution of changes in medical technology use to costs.** The aforementioned caveats having been noted, the evidence on the components of hospital and health care cost (or expenditure) inflation is presented below.

Several analysts have divided changes in *hospital costs* into their constituent parts, including service intensity (3,117,126,419,430). Waldman (419) estimated that increases in service intensity (i.e., labor, supplies, and equipment) accounted for about one-half of the annual change in the daily cost of hospital care between 1951 and 1970. Studies of increases in hospital costs per day through the mid-1970's found similar results (3, 116). Feldstein and Taylor (117), for example, found that slightly less than one-half of the rise in average daily hospital costs between 1955 and 1975 was due to an increase in the intensity of services delivered per day. Altman and Wallack (3) found that roughly one-third to one-half of the annual increase in daily hospital costs between 1971 and 1976 was the combined result of an increase in the intensity of services and an increase in the price of hospital inputs relative to general wage and price inflation.

Freeland and Schendler's recent analysis of the 283-percent increase in national expenditures for hospital care over the period 1971 to 1981 found that 59 percent of the increase could be explained by overall inflation in the economy and growth in the U.S. population (126). The remaining 41 percent of the increase in national expenditures for hospital care was due to three technology-related factors:

- increased hospital admissions per capita (8.6 percent);
- increased intensity, or input use, per admission (20.8 percent); and
- increased hospital input prices in excess of general inflation (11.7 percent).

From 1971 to 1981, these three factors raised national expenditures for hospital care about 157 percent.

Table 8 presents data on hospital cost increases for the period 1977 to 1982. OTA estimates that **increases in service intensity (labor and nonlabor imputs) per capita accounted for 24 percent of the 93-percent increase in per capita hospital costs during the most recent 5-year period.** A small part of this effect is due to the higher admission rate (a 5-year increase of 2.1 percent), but the overwhelming part of the intensity increase is due to higher intensity per hospital admission.

The results of the aforementioned analyses are summarized and compared in table 9. The estimated growth in the intensity of hospital inputs clearly depends on the time period studied and the denominator unit. However, all five analyses support the conclusion that **the intensity of hospitals' services has contributed substantially to the growth in hospital costs over the past 20 years.**

When the components of growth of total personal health care expenditures in the United States are considered, increasing intensity of care appears to be a less important source of expenditure inflation than it is for the hospital sector alone. Table 10 shows estimated growth in real per capita personal health care expenditures between 1977 and 1982 (when population growth and general price inflation, as measured by the Consumer Price Index, are taken into account). The combined effect of increasing intensity and increasing health care prices in excess of the Consumer Price Index is a relatively small proportion (about 16 percent) of the increase in per capita personal health care expenditures during the 5-year period. Nevertheless, these two technology-related components of cost together increased real per capita health care expenditures at an average annual rate of 2.8 percent during the period.

It is possible to account for the components of Medicare cost increases over an appropriate time

Table 8.—Decomposition of Hospital Costs, 1977-82

	1977	1982	Difference 1982 – 1977	Percent change 1977-1982	Average annual percent change
1. Total hospital costs (millions)	$51,647	$104,876	$53,229	103.1%	15.2%
2. Total U.S. population (thousands)	219,760	231,534	11,774	5	1.1
3. Total adjusted hospital admissions[a] (thousands)	39,012	41,947	2,935	8	1.5
4. Total full time equivalent employees (thousands)	2,573	3,306	733	29	5.1
5. Consumer Price Index (1977 = 100)	100	159.3	NA[b]	NA	NA
Service intensity per adjusted admission:					
6. Hospital costs per adjusted admission	$1,324	$2,500	$1,176	89	13.6
7. Nonlabor costs per adjusted admission	$563	$941	$378	92	13.9
8. Nonlabor inputs per adjusted admission (7 ÷ 5)	$563	$591	$28	21	3.8
9. Labor costs per adjusted admission	$761	$1,421	$660	87	13.3
10. Index of hospital labor costs per full time equivalent employee (1977 = 100)	100	156	NA	NA	NA
11. Labor inputs per adjusted admission (9 ÷ 10)	$761	$910	$149	19	3.6
12. Change in labor and nonlabor inputs per adjusted admission (8 + 11)	NA	NA	177	NA	NA
Service intensity per capita:					
13. Hospital costs per 1,000 population	$235	$453	$218	93	14.0
14. Nonlabor costs per 1,000 population	$100	$196	$96	95	14.3
15. Nonlabor inputs per 1,000 population (14 ÷ 5)	$100	$123	$23	23	4.2
16. Labor costs per 1,000 population	$135	$257	$122	92	14.0
17. Labor inputs per 1,000 population (16 ÷ 10)	$135	$164	$29	21	4.1
18. Change in labor and nonlabor inputs per capita (15 + 17)	NA	NA	52	NA	NA

[a] Adjusted admissions include outpatient visits, which are weighted in equivalent units.

[b] NA—Not applicable.

Data sources:

1. Most data derived from American Hospital Association, *Hospital Statistics*, table 6, 1978 and 1983 editions.
2. Population data from U.S. Department of Commerce, *U.S. Statistical Abstract*.
3. Consumer Price Index found in U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1982*, DHHS publication No. (PHS) 83-1232 (Hyattsville, Md.: DHHS, December 1982).

SOURCE: Office of Technology Assessment.

Table 9.—Summary of Studies of Hospital Cost Inflation

	Source and study period covered				
	Waldman 1951-70	Feldstein 1955-75	Altman & Wallack 1971-76	Freeland & Schendler 1971-81	OTA 1977-82
Hospital cost per patient day:					
Annual average percent change	8.6% per year	12% per year	17.1% per year	—	—
Proportion due to service intensity	50%	48%	30.6 to 50.5%	—	—
Hospital cost per admission:					
Annual average percent change	—	—	—	13% per year	13.2% per year
Proportion due to service intensity	—	—	—	20.8%	15%
Hospital cost per capita:					
Annual average percent change	—	—	—	—	14.0% per year
Proportion due to service intensity	—	—	—	—	24%

Data sources:

1. S. Waldman, "The Effect of Changing Technology on Hospital Costs," *Research and Statistics Note*, Social Security Administration, Office of Research and Statistics, DHEW publication No. (SSA) 72-11701, Feb. 28, 1972.
2. M. S. Feldstein, *Hospital Costs and Health Insurance* (Cambridge, Mass.: Harvard University Press, 1981).
3. S. H. Altman and S. S. Wallack, "Technology on Trial—Is It the Culprit Behind Rising Health Costs? The Case For and Against," in *Medical Technology: The Culprit Behind Health Care Costs*, proceedings of the 1977 Sun Valley Forum on National Health, DHEW publication No. (PHS) 79-3216, 1979.
4. M. S. Freeland and C. E. Schendler, "National Health Expenditure Growth in the 1980's: An Aging Population, New Technologies, and Increasing Competition," *Health Care Financing Review* 4(3):1-58, March 1983.

SOURCE: Office of Technology Assessment.

Table 10.—Increase in Personal Health Care Expenditures,[a] 1977-82

	1977	1978	Percent change	1979	Percent change	1980	Percent change	1981	Percent change	1982	Percent change	Average annual percent change 1977-82
1. Total personal health care expenditures (billions)	$148.7	$166.7	12.1%	$188.9	13.3%	$219.4	16.1%	$255.0	16.2%	$286.9	12.5%	14.0%
2. U.S. population (millions)	220	222	0.9	225	1.4	227	0.9	229	0.9	22	1.3	1.1
3. Personal health care expenditures per capita	$657.9	$750.9	11.1	$839.6	11.8	$996.5	15.1	$1,113.5	15.2	$1,236.6	11.0	12.8
4. Consumer Price Index	100.0	107.6	7.6	119.9	11.4	136.1	13.5	150.0	10.2	159.3	6.2	9.8
5. Medical care index (1977 = 100) (12-month period ending September)	100.0	108.5	8.5	118.3	9.1	131.0	10.7	146.1	11.5	162.2	11.0	10.2
6. Real personal health care expenditures per capita (3 ÷ 4)	$675.9	$697.9	3.3	$700.3	0.3	$710.1	1.4	$742.3	4.5	$776.3	4.6	2.8
7. Real health inputs per capita (service intensity (3 ÷ 5)	$675.9	$692.1	2.4	$709.7	2.5	$737.8	3.9	$762.1	3.2	$762.4	0.1	2.4

[a] Personal health care expenditures are national health care expenditures minus administrative costs.

Data sources:

1. Total health care expenditure data for 1977 to 1981, U.S. Department of Health and Human Services, National Center for Health Statistics, *Health—United States, 1982*, DHHS publication No. (PHS) 83-1232 (Hyattsville, Md.: DHHS, December 1982).
2. 1982 health care expenditure data, U.S. Department of Health and Human Services, Health Care Financing Administration, Statistical Information Services, personal communication, Sept. 1, 1983.
3. U.S. population, U.S. Department of Commerce, *U.S. Statistical Abstract*.
4. Medical care price index, U.S. Department of Health and Human Services, Health Care Financing Administration, *Health Care Financing Trends*, DHHS publication No. 03091, winter 1981.
5. 1981 and 1982 medical care index data, U.S. Department of Commerce, Bureau of Labor Statistics, personal communication, Sept. 1, 1983.

SOURCE: Office of Technology Assessment.

interval, but the interpretation of the estimates is more clouded than it is for general health care costs. Changes in program eligibility, such as the inclusion of disabled people in 1972, or in covered benefits, such as the expansion of home health care benefits in 1980, can lead to dramatic changes in measured service intensity that have little to do with changes in medical technology but instead represent a shift in the burden of payment for services already available and used. Changes in per capita service intensity do indicate how much more or less of health care services Medicare is paying for now than at some earlier date. Table 11 provides per capita estimates for 1977 and 1982.

The data presented in table 11 indicate that most of the 107-percent increase in Medicare expenditures per enrollee between 1977 and 1982 is due to general price inflation. **But 25 percent of the increase in Medicare expenditures per enrollee from 1977 to 1982 is due to Medicare's payment for more services per enrollee, and another 3 percent is due to the increased prices of medical services in excess of general price inflation.[6] Thus, nearly 30 percent of the increase in Medicare costs per enrollee from 1977 to 1982 can be attributed to two technology-related components of costs.**

Table 11.—Real Medicare Expenditures per Enrollee, 1977 and 1982

	1977	1982
1. Medicare expenditures per enrollee	$927.54	$1,925.40
2. Consumer Price Index (1977 = 100)	100.00	159.30
3. Medical care price index (1977 = 100)	100.00	162.40
4. Real Medicare expenditures per enrollee (1 ÷ 2)	$927.54	$1,208.66
5. Real Medicare inputs per enrollee (1 ÷ 3)	$927.54	$1,185.59

Data sources:
U.S. Department of Health and Human Services Health Care Financing Administration, *The Medicare and Medicaid Databook, 1981*, HCFA publication No. 03156 (Baltimore, Md.: HCFA, April 1982). U.S. Department of Health and Human Services, Health Care Financing Administration, Office of Statistical Information, personal communication, Sept. 1, 1983; U.S. Department of Commerce, Bureau of Labor Statistics, personal communication, Sept. 1, 1983.

SOURCE: Office of Technology Assessment.

Other Estimates of Technology's Contribution to Health Care Costs

The service intensity approach has its limitations as a way of estimating technology's contribution to health care costs. A few analysts have used different approaches and data bases to look at the question.

Redisch (267), for example, analyzed cost and operating data for a sample of about 1,500 hospitals and found that approximately 40 percent of the rise in operating costs per admission resulted from the increased use of eight types of ancillary services, all of which must be ordered by the physician. (The services were pathology, nuclear medicine, anesthesiology, pharmacy, laboratory, diagnostic X-ray, therapeutic X-ray, and blood bank.) Whether the increased use of ancillary technologies in the hospital has corresponded to reductions in the cost of other kinds of health care, however, is unknown.

Several analysts have used a "residual approach" to measure the impact of technological change on hospital or health care expenditures. In this approach, expenditures over time are regressed on a number of variables influencing supply or demand for health care services.[7] The unexplained residual of changes over time is then assumed to measure the effect of technological change.

In a study of hospital costs from 1962 to 1968, Davis (82) found that 38 percent of the total annual increase in hospital cost per admission was unexplained by variables reflecting supply and demand conditions. This residual translates into a 2-percent annual increase in hospital expenses per admission attributed to technological change.

Other analysts have used the residual approach to estimate the impact of technological change on total health care costs (130,231). In one study, which covered the period 1930 to 1975, Mushkin and colleagues (231) estimated that technological change *reduced* total health care expenditures at an annual rate of 0.5 percent. In a similar study, which covered the period 1947 to 1967, however, Fuchs (130) found that technological change *raised* expenditures at an annual rate of 0.6 percent.

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[6] The percent due to medical price inflation may be overstated, and the service intensity percentage correspondingly understated, because the amount Medicare actually pays for services (i.e., the effective price) probably lies somewhat below stated prices.

[7] In the regression process, each variable receives a weight that represents the relative degree to which that variable explains or contributes to the change in expenditure. Some percent of the change cannot be explained by the variables. This percent is called the residual.

The difference in the findings of these two studies could, as Mushkin claimed, be due to differences in the periods studied or the variables chosen for study. Altman and Wallack (3) have pointed out significant limitations of the approach used in both studies. One limitation is the sensitivity of any residual estimate to the variables chosen for inclusion. In Altman and Wallack's words, "even relatively small errors in specification [of the variables chosen] or in the statistics used to estimate the model can lead to the conclusion that technology has had a positive impact on rising health care costs when the true result is negative, or vice versa" (3). An even more important limitation of the approach is the narrow interpretation of technological change embodied in the residual. A major portion of the increased use of medical technology may well be attributed to demand-related factors such as the growth of third-party payment or personal income over the periods of study. Since these variables were included as variables in the regressions, the contribution to health care costs of changes in medical technology is underestimated. In short, the residual approach gives too narrow a view of just how changes in the quantity, quality, kinds, and settings of use of medical technology have influenced health care costs.

Another useful approach to looking at technology's impact on health care costs is to focus on a specific illness and to document the array of medical practices and procedures used to treat the condition at two different times. The costs of treating the illness using the practices current in each time period can be estimated, and the difference in these costs can be considered the effect of technological change on the cost of illness. However, it should be noted that this approach does not account for changes in the rates of use of treatments. Furthermore, only a few conditions can be studied because of the high cost of this kind of analysis. Trends detected in studies of a few illnesses certainly do not represent all illnesses and may not even represent the most important ones.

Scitovsky and McCall (298) took this approach to explain the net increase from 1964 to 1971 in the average cost of treatment for eight conditions: otitis media, forearm fracture, appendicitis, maternity care, breast cancer, pneumonia, duodenal ulcer, and myocardial infarction. In almost every instance, there were both cost-raising and cost-saving changes in treatment. However, the authors noted that the costs of treatment of conditions requiring hospitalization rose at a considerably faster rate than those of conditions treated on an ambulatory basis. Among the factors leading to higher costs were shifts to more expensive drugs, increases in the number of laboratory tests per case, and the use of more miscellaneous inpatient and outpatient services. The most dramatic cost increases occurred in the treatment of myocardial infarction, traceable principally to the increased use of ICUs during the time period.[6] The increase in the cost of treating this condition was greater than the decrease in the costs of five other illnesses combined. Of course, the net effect on health care costs would depend on the relative frequency of the various conditions in the population.

Conclusions From the Aggregate Studies

Although none of the approaches to measuring technology's aggregate contributions to health care cost is entirely satisfactory, **taken as a whole, the available evidence leads to the conclusion that U.S. health care costs have increased in part because more is being done for patients today than ever before.** More and better trained personnel, more procedures, more medicines, and more and higher priced equipment, materials, and supplies are being used in the delivery of health care to Medicare patients and to the Nation as a whole. And, the trend toward "more" is not abating. The intensity of service use continues to increase.

Despite the net increase in service intensity, the evidence also demonstrates the variation in tech-

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[6] For more information, see the forthcoming case study in OTA's Health Technology Case Study Series entitled *Intensive Care Units (ICUs): Costs, Outcomes, and Decisionmaking* (354), prepared by Robert A. Berenson, M.D.

nology's effects on costs. In the past 5 years, the hospital sector appears to have experienced relatively greater increases in intensity than has the health care sector as a whole. And, as Scitovsky and McCall's (298) research illustrates, cost-raising and cost-saving changes in technology are not scattered evenly across illnesses. **The real cost of treating some illnesses has declined as a result of technological change, while that of others has increased dramatically.** Thus, summary statements about technology's net influence on health care or Medicare costs mask the rich assortment of ways in which changes in medical technology shape the health care system and its costs.

SELECTED MEDICAL TECHNOLOGIES AND MEDICARE COSTS

To highlight the extent to which the costs of the Medicare program are altered by new technologies, this section describes seven technologies first introduced in the 1960's or 1970's and examines their actual and potential impact on Medicare costs. The seven technologies are:

- coronary artery bypass graft surgery,
- the drug cimetidine,
- therapeutic apheresis,
- pneumococcal vaccine,
- intensive care units,
- parenteral nutrition therapy, and
- kidney dialysis.

All seven of the technologies have clear patient benefits—in some cases, they are even life saving—but for all of them, there are uncertainties about the most appropriate indications for use. Five of the technologies have raised or could raise Medicare's costs, in some cases significantly. Two have saved or could save Medicare costs. Above all else, these seven technologies illustrate how exposed the Medicare program is to changes in medical technology that are largely beyond its control. In the face of new technologies that offer both patient benefits and higher costs, the challenge for Medicare may be how to encourage the use of those that are most cost effective.

Coronary Artery Bypass Graft Surgery

Coronary or arteriosclerotic heart disease, often caused by narrowing and blocking of the arteries that supply blood to the heart, is the number one cause of death in the United States. In 1982, heart disease was responsible for approximately 500,000 deaths (408). Furthermore, in 1968, this disease was the most frequent condition diagnosed for patients at the time of discharge from hospitals in this country (198).

Coronary artery bypass graft surgery (CABG), a procedure in which a graft is used to bypass a constricted portion of the coronary artery and thus to improve oxygen supply to the heart muscle, has become the primary surgical approach to treatment of coronary artery disease (53). Since coming into practice in the early 1970's, the procedure has diffused quite rapidly: approximately 25,000 operations were performed in the United States in 1973; at least 70,000 in 1977; 86,000 in 1979; 100,000 in 1980 (266); and 170,000 in 1982 (87,341). The rate of CABG in the United States has been estimated to be from 4 to 10 times as high as that of the United Kingdom, although the incidence of coronary artery disease is similar in the two countries (266,297).

Data from a 15-institution registry of patients undergoing evaluation for suspected coronary artery disease during the period from 1974 to 1979 reveal that 10 percent of such patients were 65 years of age or older (186). About 15.2 percent of the bypass procedures performed in Maryland in 1980 were on patients 65 or older (68). However, 1982 data from the National Hospital Discharge Survey suggests that almost 30 percent of all such procedures were performed on those 65 years of age or older (87).

Almost all evaluations of CABG have shown that the surgery is more effective than medical management in relieving angina pectoris (a condition characterized by severe chest pain). After surgery, angina is lessened in 80 to 90 percent and totally relieved in 60 to 70 percent of patients. The available data can be interpreted as suggesting that surgery is far more effective than medical management in improving that aspect of quality of life (266). Two clinical evaluations have demonstrated the life-extending properties of CABG in patients with coronary artery disease involving three vessels or the left main coronary artery, but the life-extending properties of the procedure are more uncertain when only one or two arteries are involved and when left ventricular function is severely restricted (422). Recently, the results of a clinical trial covering 15 medical centers revealed that CABG has not been shown to extend life in patients with mild or no chest pain and should probably be delayed until chest pain increases. The trial included patients under 65 years of age who did not have narrowed left main coronary arteries and who had mild or moderate chest pain, or those who had had at least one heart attack already but no chest pain. The investigators found no difference in mortality between medical and surgical management. Patients with surgery had greater relief from chest pain and better exercise tolerance, but the surgical group was hospitalized more often. Perhaps most telling, chest pain gradually worsened in both groups, and since a second operation is more hazardous than the first, the investigators concluded that "there is no penalty for waiting." The investigators estimate that about 25,000 of the 170,000 CABG procedures performed in 1982 would be contraindicated by these findings (192).

CABG itself is costly, estimated at approximately $15,000 to $20,000 in 1981, including hospital and surgical fees (422). But, the surgery also saves part of the costs of medical management of coronary artery disease and avoids the cost of treating heart attacks that are prevented by the surgery. When these savings in medical costs are taken into account, the net costs associated with CABG surgery range from $10,000 to $19,000, depending on the presenting condition of the patient (422).

If the age distribution of bypass surgery patients in the United States follows that reported by the National Hospital Discharge Survey, then approximately 50,000 procedures were performed on Medicare's aged population in 1982. This would imply that the procedure cost the Medicare program and its beneficiaries approximately $500 million to $950 million in that year.[9] At this cost, Medicare buys for some elderly patients substantial benefits in the form of improved quality and extra years of life. For a substantial minority (estimated at 15 percent or 7,500 procedures), the procedure may offer little in the way of improvement. Thus, an estimated $75 million to $142 million of the 1982 expenditures by or on behalf of Medicare patients for CABG surgery may have been unnecessary. Even disregarding these potentially excess costs, CABG has had a substantial impact on annual Medicare costs.

Cimetidine

Peptic ulcer disease is a relatively common illness with important ramifications for Medicare. In 1976, about 620,000 hospital discharges in the United States were for peptic ulcer, representing a rate of about 175 per 100,000 people (432). Furthermore, over 25 percent of the hospital stays for peptic ulcer involved surgery (433). The incidence of peptic ulcer disease increases with age (119). In 1978, fully 40 percent of hospital days of care for ulcer disease were for those 65 years or older (see table 12). In addition, the rate of ulcer-related surgery was twice as high for the elderly as for the general population (see table 13). In 1975, the total direct and indirect costs of ulcer disease in the United States were roughly estimated to be in the neighborhood of $2 billion (121).

In August 1977, a new drug was approved for use in the United States for the short-term treatment of duodenal ulcers.[10] This drug, known as cimetidine, acts by blocking stimulation of gastric acid secretion. Clinical evidence has demonstrated that cimetidine promotes healing of ulcers compared to placebo (121).

Several analysts have investigated cimetidine's impact on the use of health services. Studies in the United States and abroad have documented

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[9] Although not all of the costs of an individual surgery occur during the year in which the procedure is performed, the estimate is reasonably accurate for the Medicare population as a whole.

[10] In 1976, duodenal ulcers accounted for approximately one-half of all hospitalized peptic ulcer cases in the United States. Gastric and unspecified ulcers accounted for the other half.

Table 12.—Days of Care for Ulcer Disease for Patients Discharged From Short-Stay Hospitals, 1977-79 (per 100,000 population)

	1977		1978		1979	
ICDA code	All ages	≥65 years	All ages	≥65 years	All ages	≥65 years
531—Stomach ulcer	524.6	2,119.5	484.1	2,186.0	412.3	1,773.3
532—Duodenal ulcer	751.3	2,554.1	636.9	2,220.2	559.7	1,955.5
533—Peptic ulcer	294.4	940.4	263.9	871.4	248.4	708.5
534—Gastrojejunal ulcer	30.5	140.5	37.3	90.3	30.7	105.3

Data sources:
U.S. Department of Health and Human Services, National Center for Health Statistics, "Detailed Diagnosis and Surgical Procedures for Patients Discharged From Short-Stay Hospitals: United States," for years 1977, 1978, and 1979 (Hyattsville, Md.: DHHS).

SOURCE: Office of Technology Assessment.

Table 13.—Operations for Ulcer Disease for Patients Discharged From Short-Stay Hospitals, 1977-79 (per 100,000 population)

	1977		1978		1979	
ICDA procedure	All ages	≥65 years	All ages	≥65 years	All ages	≥65 years
46.2—Partial gastrectomy	24.1	77.7	18.5	37.7	4.0	8.1
46.8—Vagotomy	21.5	46.9	13.6	26.2	1.8	8.1

Data sources:
U.S. Department of Health and Human Services, National Center for Health Statistics, "Detailed Diagnosis and Surgical Procedures for Patients Discharged From Short-Stay Hospitals: United States," for years 1977, 1978, and 1979 (Hyattsville, Md.: DHHS).

SOURCE: Office of Technology Assessment.

reductions in duodenal ulcer surgery rates immediately following the introduction of cimetidine in 1977. Fineberg and Pearlman (122) estimated that in 1978 the number of surgeries in the United States was 21,000 to 31,000 less than would have been predicted from the trend prior to 1977. In 1979 and 1980, the number of procedures was below the expected rate (but there was no statistical significance) (122,312). Thus, cimetidine may delay surgery to a greater extent than it replaces it.[11]

The introduction of cimetidine coincided with a dramatic decrease in the rate of hospitalization for peptic ulcer disease in young adults (15 to 44 years old). There was only a modest decrease in the rate for all patients in the United States between 1977 and 1978 (432). This fact suggests that the elderly population may not have experienced a substantial reduction in hospitalization as a result of the drug's availability.

A recent analysis reported on the impact of cimetidine on the costs of ulcer disease in Rhode Island (272). Although this study was limited by the available data, the researchers had access to hospital charges for patients undergoing ulcer surgery. Ulcer surgery rates declined in Rhode Island after the introduction of cimetidine, and a proportion of this decline was ascribed to cimetidine's availability. The authors estimated that this reduction in surgery meant statewide savings in medical care of between $185,000 and $450,000, depending on the extent to which it can be assumed that a reduction in surgery keeps ulcer patients out of the hospital.

The evidence on the economic evaluation of cimetidine reviewed above highlights the impact that a single drug can have on the patterns of hospital and medical care. It also demonstrates the difficulty of determining whether these changes in patterns of use save health care or Medicare costs without the passage of enough time to monitor such changes. Today, physicians prescribe cimetidine for a variety of indications that are not among those approved by the Food and Drug Administration, including prevention of gastrointestinal bleeding in hospitalized patients (63,290). The economic impact of cimetidine in these areas has not been investigated, yet it could surpass the effects of cimetidine in treating ulcer disease.

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[11] It is important to note that the expected surgery rate in the absence of the cimetidine was calculated on the basis of a declining linear time trend. It is questionable whether such a trend would normally continue as rates of surgery decline to low levels. One might expect surgery rates to level off at some point in time.

Therapeutic Apheresis[12]

Therapeutic apheresis is not a new procedure, but the extent of its use has grown rapidly during the past 5 years. It is a procedure in which a patient's plasma or blood cellular parts or both are separated and then removed from the blood and most often replaced by substitute plasma or a related physiological solution. It is believed that abnormal or harmful substances or cells are thereby removed, leading to a cure or arrest of disease. At present, apheresis is primarily accepted as an acute therapy in a small group of relatively obscure diseases, and the number of patients undergoing treatment is approximately 20,000 (183). Results reported in the scientific literature have been dramatic, and apheresis is being used to treat an increasing number of medical conditions. Skepticism over the validity of such claims along with the high costs of apheresis, however, have touched off recent controversies over this procedure's use.

From 1977 through 1980, procedure volume increased more than 700 percent, from around 5,000 to over 40,000 procedures per year. In the late 1970's, the rate of growth far outpaced the estimates. For example, the now defunct National Center for Health Care Technology originally estimated its use in 1979 at "hundreds of procedures. It turned out to be around 16,000. A lot of people were doing it but not reporting it" (95).

The costs of apheresis have become a particularly volatile issue. Each treatment costs between $400 and $1,200. Furthermore, each patient requires a number of treatments, usually varying between 5 and 15. (Sometimes as many as 30 treatments are needed initially, but the number tapers off with time.) Estimates of current national expenditures on apheresis therapy range from $3.2 million to $240 million. If apheresis therapy is extended in the future to the wider array of diseases to which it has been only experimentally applied thus far, total national treatment costs could range from $650 million to over $7 billion per year (349).

In 1981, the Health Care Financing Administration (HCFA) issued the first national instructions on the coverage of apheresis under Medicare. Only a small group of relatively rare diseases were listed as acceptable indications for the procedure. These included: myasthenia gravis; leukemia; and macroglobulinemia and hyperglobulinemias, including multiple myeloma (382). In 1983, a few additional uses were added to the list, including thrombotic thrombocytopenic purpura as a last resort treatment; life-threatening rheumatoid vasculitis; life-threatening forms of Goodpasture's syndrome, when the patient has not responded to more conventional forms of therapy; and glomerulonephritis, when the patient has not responded to more conventional forms of therapy (74). Moreover, Medicare coverage of apheresis has been limited only to procedures performed in the hospital inpatient or outpatient setting.

The ultimate cost of therapeutic apheresis to the Medicare program will depend on whether coverage is extended to new indications and on the distribution of the affected diseases in the elderly population. By far the largest potential cost will arise if therapeutic apheresis is used for those who suffer from rheumatoid arthritis, which afflicts an estimated 5 million to 7 million people in the United States. Most observers believe that apheresis would be used on patients who have failed to respond to traditional forms of therapy. At present, the consensus of professional opinion is that apheresis for treatment of rheumatoid arthritis is an experimental therapy (349). Clinical evaluation of the use of this procedure in rheumatoid arthritis has been limited, but one controlled study found no statistically significant differences between the short-term response of patients receiving apheresis together with drug therapy and the response of patients receiving drug therapy alone (287).

Pneumococcal Vaccine

An estimated 10 to 35 percent of all cases of pneumonia are bacterial infections caused by pneumococci (358). There are over 80 known serotypes of pneumococcal bacteria (293), but a much smaller number is responsible for the majority of pneumococcal pneumonias in the world.

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[12] This section is based on a case study prepared for this project by OTA, entitled *The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis* (349).

Vaccines for various combinations of pneumococcal serotypes have been produced at different points in time since the turn of the century, but in 1978, a vaccine offering protection against 14 serotypes of pneumococcal bacteria responsible for about 70 to 85 percent of pneumococcal infections was introduced into commercial production (18). At the time of the vaccine's introduction, immunizations were specifically excluded as Medicare benefits by Section 1862 of the Social Security Act.

The ultimate potential for the pneumococcal vaccine is uncertain because of a lack of knowledge about the incidence of pneumococcal pneumonia in various population groups, the distribution of pneumococcal serotypes in these pneumonias, and the effectiveness of the vaccine in various patient groups, particularly high-risk groups (18,168). It is unknown, for example, whether a reduction in pneumococcal infections of the 14 types contained in the vaccine will be met with a concomitant increase in the incidence of other types of pneumococcal pneumonia, especially in high-risk patients (31). Since estimates of economic costs must rely on estimates of these rates, they are themselves subject to a great deal of uncertainty.

In 1979, noting these data and methodological problems, OTA performed a cost-effectiveness analysis of a pneumococcal vaccination program (358). OTA's analysis compared the net societal medical care costs and health effects (measured in terms of quality-adjusted life-years) that would result from vaccination. Under the base case set of assumptions, vaccination would increase net medical care costs[13] for vaccinees in all age groups, but would also yield health benefits that could not be obtained through treatment. Furthermore, vaccination of the elderly (those 65 years of age and older) was relatively cost effective in comparison to many existing health programs.

Working largely with data provided by OTA, the Congressional Budget Office analyzed the likely impact of covering the pneumococcal vaccine as a Medicare benefit on Medicare expenditures (331). That study found that a vaccine benefit would be cost saving to Medicare after 3 to 5 years, depending on the assumptions made about vaccination rates, levels of reimbursement for vaccination, and the inclusion of medical costs arising from increased life spans.

Partly as a result of these analyses Congress amended the Social Security Act to allow Medicare coverage of pneumococcal vaccination. At present, it appears that vaccination rates in the Medicare population are low, and estimates of Medicare cost impacts are not available (305).[14]

Intensive Care Units

The ICU is an example of a technology which has proliferated widely despite the absence of studies of efficacy or cost effectiveness. Because of the difficulty of separating the intensity of care from the setting in which it is provided, it is difficult to know whether intensive care would be as effective if provided on the general hospital floor as in the physically and administratively separate ICU. For many medical problems, however, treatment in an ICU has become the standard method of treatment.

A recent National Institutes of Health sponsored consensus panel concluded that it is impossible to generalize about whether ICU care improves outcome for the varied ICU patient population. The panel agreed that ICU intervention is unequivocably lifesaving for some conditions, particularly where there is an acute, reversible problem, such as drug overdose or major trauma. It was less certain about the effectiveness of ICU care in other conditions, particularly in the presence of a severe, debilitating chronic illness, such as cancer or cirrhosis of the liver (409).

Despite the uncertainty about the indications for ICU care, almost 80 percent of short-term general hospitals have at least one ICU (354). Large hospitals are likely to have two or more ICUs, organized along specialty lines. Overall, 5.9 percent of total hospital beds in non-Federal, short-term community hospitals in 1982 were beds in adult intensive and coronary care units (9). In 1980, 7 percent of hospital Medicare charges were for intensive and coronary care units (161). This figure understates the full costs of ICU care because it does not include the ancillary charges for patients. In any case, it is a representation of charges instead of costs, which may be higher. It is estimated that the costs of adult intensive and coronary care unit care represent over 15 percent of total hospital inpatient costs, or $4,742.5 million in 1982 (354). Inclusion of the other types of specialized ICUs, such as neonatal and burn care units, would bring the percentage up to about 20 percent of total hospital costs, or almost 1 percent of the Nation's gross national product.

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[13] OTA's analysis included the discounted value of future medical care costs arising from increased life expectancy among vaccinees.

[14] For more information, see OTA's forthcoming technical memorandum *Update on Federal Activities Regarding the Use of Pneumococcal Vaccine*, OTA-TM-H-23 (Washington, D.C.: U.S. Government Printing Office, May 1984).

According to 1979 Medicare data, 18 percent of Medicare discharges included a stay in intensive or coronary care units (160). From reports from individual hospitals, it appears that the representation of the elderly Medicare population in ICUs is about the same as in the hospital as a whole (354). Age alone does not appear to be a significant factor limiting use of ICUs in the United States. It is noteworthy that in other countries, ICU patients have a significantly lower mean age (354).

The literature on the outcomes of ICU care has demonstrated consistently the inverse relationship between the cost of ICU care and the likelihood of survival. The sickest ICU patients, many of whom do not survive their hospital stay, consume a disproportionately high share of ICU costs. Under Medicare's cost-based hospital reimbursement system, the high-cost patients were not particularly burdensome financially to the hospital. However, under Medicare's recently initiated prospective payment system for inpatient hospital care, many of these long-stay, high-cost ICU patients will become financial losers to the hospital (354).

Total Parenteral Nutrition

Total parenteral nutrition (TPN) refers to the intake of nutrients directly into the bloodstream, circumventing the digestive tract (14). Its primary use is in eliminating malnutrition in patients who cannot adequately digest food or whose nutritional needs are elevated because of disease or injury. To receive TPN, a patient must have his or her nutritional needs assessed by a doctor or dietician and must have a catheter implanted in a large vein.

Clinically, a patient must be on TPN for a variety of reasons, most commonly inflammatory bowel disease (e.g., Crohn's disease), ischemic bowel infarction, and cancer-related problems, including damage due to radiation therapy (158). Indications for the use of TPN have been the subject of considerable discussion in the medical profession in the last 5 years. Some physicians advocate the use of TPN to bolster patients before surgery and to improve cancer patients' tolerance to therapy. Others suggest that TPN has little influence on the outcome in these cases and may actually promote tumor growth (139,181).

Before the late 1960's, prolonged maintenance of patients with digestive dysfunction was not possible. The development of TPN came about through advances made in four areas: improved knowledge of human nutritional needs, improved surgical procedures, improved catheter composition and design, and improved infusion control devices. The development of volumetric infusion pumps, especially the cassette-type electronic pump introduced in 1974, was the watershed for safe and reliable infusion that made overnight parenteral feeding practical.

TPN can be delivered either in the hospital or in the home. Before 1979, all home TPN patients were treated as hospital outpatients. In that year, a private firm, Home Health Care of America, entered the market, offering a package of supplies and services (189). Today there are some 30 to 40 commercial home TPN providers, several of which are owned by firms that manufacture solutions and supplies (37).

In either setting, hospital or home, TPN is an expensive long-term therapy. A study at the Cleveland Clinic found that costs to the hospital for home TPN were about one-fourth of TPN costs in the hospital, but even in the home, the average per-patient first-year costs were estimated at $21,465 (in 1978 dollars) (421). The most important factor in cost was the quantity of disposable supplies, including nutritional solutions, which accounted for almost 90 percent of the total cost. Other studies have estimated costs of a typical home TPN patient to be about $40,000 to $45,000 per year (158,189,301).

Medicare coverage of TPN delivered to hospital inpatients has never been at issue. TPN provided in a hospital setting has been covered as a Part A hospital benefit since the technology was developed. In 1977, HCFA began to cover home TPN on the advice of the Public Health Service. At that time, HCFA did not anticipate home TPN as a major expense; it was expected that only about 10 patients per year would need home coverage and that most of these patients would not live long (56). Because intravenous nutrients are classified as drugs and are therefore not individually reimbursable under Medicare's Part B, HCFA declared the whole home TPN system a prosthetic device, and therefore subject to Part B coverage. In 1981, HCFA tightened the requirements for home TPN, listing seven diagnoses for which it was appropriate. Other indications can be approved on a case-by-case basis (62,184).

All persons eligible for Medicare and participating in the Part B program are covered for home TPN supplies. Persons younger than 65 and not otherwise eligible can receive Medicare coverage if their need for home TPN renders them unable to work, but over half of home patients consider themselves fully functional once they receive the needed nutrition (241). TPN covered under Part B is reimbursed on the basis of reasonable charges, but because there have been relatively few home TPN patients, it has been difficult to establish charge screens. As with other Part B services, TPN at home is subject to the deductible and coinsurance provisions of Medicare.

The use of home TPN has undergone tremendous growth in recent years, much of which was stimulated by the increase in coverage by Medicare and other insurers. For example, a registry maintained by the New York Academy of Medicine reported a 103-percent increase in the number of patients on home TPN between 1979 and 1981 (241). It has been estimated that about 200 TPN patients were discharged to the home in 1978 (301), while estimates for 1983 are around 4,000 home patients (37). It is unknown to what extent this increase represents a substitution of home TPN for inpatient nutrition services and to what extent it represents a net increase in the number of patients receiving TPN.

The home parenteral nutrition registry estimates that about 22 percent of patients receiving home TPN in 1979 were Medicare enrollees (241). If the cost estimate of $40,000 per year for TPN in the home is accepted, and if it is assumed that 22 percent of the 4,000 patients on home TPN are Medicare beneficiaries, then Medicare currently pays in the neighborhood of $28 million per year for home TPN.[15] A lack of data precludes estimation of the total cost to Medicare of providing TPN in the hospital, but it is likely to be greater than that for home TPN.

Although over $28 million in annual Medicare expenditures for a technology that extends life is small in relation to total Medicare expenditures ($52.2 billion in 1982), this case illustrates the extent to which the impact on Medicare cost of a new technology can be grossly underestimated at the time coverage is introduced.

Hemodialysis for Chronic Renal Failure

Hemodialysis represents the classic case of a lifesaving technology whose development dramatically affected the costs of Medicare. Although hemodialysis has been available since 1945 for temporary treatment of acute and reversible renal failure, its application to patients with end-stage renal disease (ESRD) was first made possible in 1960, when Quinton and Scribner developed a subcutaneous arteriovenous shunt (a plastic tube connected to an artery and a vein in the arm or leg) (271). Without the shunt, filtering the blood as often as necessary was not possible on a long-term basis because the blood vessels would collapse. In the early 1960's, hemodialysis became accepted as a life-extending therapy for victims of chronic kidney failure.

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[15] (0.22 × 4,000 × $40,000 × 0.80).

The cost of hemodialysis for ESRD varies with the setting in which treatment is provided. One study estimated that the costs of dialysis in 1980 were approximately $25,000 per patient year for in-center treatment and $13,000 per patient year for home treatment after the first year (279).

Because of the high costs and the obvious life-extending properties of both hemodialysis and its competitor, kidney transplantation, a debate began in the mid-1960's over who should be responsible for paying for treatments of patients with ESRD. The debate culminated in 1972 with the passage of the Social Security Amendments (Public Law 92-603), which extended Medicare coverage of treatment for ESRD to over 90 percent of the ESRD population. Factors that led to the congressional decision to pay for ESRD treatment included a recognition that the alternative to life sustainment by dialysis or kidney transplantation was death, that ESRD treatment was very expensive, and that there occurred 7,000 to 10,000 uremic deaths a year because of the limited availability of dialysis facilities.

Photo credit: National Kidney Foundation, Washington, D.C.

Hemodialysis is a lifesaving medical technology that has affected the costs of the Medicare program

In 1972, 40 patients per million population were receiving long-term hemodialysis treatment in the United States, almost entirely under the auspices of nonprofit organizations. The number now exceeds 200 per million population (a fivefold increase) and is one of the highest in the world (96,269).

The cost of Medicare's ESRD program grew from $250 million in 1974 to an estimated $1.8 billion in 1982 (378), greatly exceeding original congressional estimates of the potential costs (279). In 1979, benefit payments for ESRD exceeded 5 percent of total Medicare expenditures and were fully 10 percent of expenditures from the Supplemental Medical Insurance fund of Medicare, although renal patients constitute only 0.2 percent of the Medicare population (38,279).

CONCLUSIONS

The evidence presented in this chapter was intended to illuminate how changes in medical technology alter the cost of the Medicare program. **Although its aggregate impact on Medicare costs cannot be estimated precisely, medical technology has clearly added to the costs of the Medicare program and to health care costs as a whole.** Today, Medicare is buying more services for its beneficiaries than ever before, and the pressure to adopt new beneficial but cost-raising technologies continues. Despite this conclusion, **the increase in the provision of services to Medicare beneficiaries and inflation in the price of medical care represent less than a third of the 107-percent increase in Medicare expenditures per capita from 1977 to 1982.** Increases in enrollment and general price inflation account for the bulk of Medicare expenditure inflation.

The descriptions of the seven new medical technologies provided in this chapter highlight the difficulty of predicting at the outset how technological change in medicine is likely to affect Medicare costs in the future. New technologies are and will continue to be developed regardless of Medicare's policies. Some of them substantially prolong life or improve its quality for Medicare beneficiaries. **Application of new technologies to the Medicare population can have large and unanticipated impacts on Medicare expenditures.** But the cases demonstrate quite clearly that **the extent of impact on Medicare program expenditures depends on whether Medicare chooses to cover a technology, and if it chooses to, to influence the conditions under which it is used.**

It is important to note that changes in service intensity are measures of the incremental effects, not the cumulative effects, of technology on total Medicare costs. It is not just at the margin that there is an opportunity to reduce Medicare costs by altering the patterns of technology adoption and use; **there are many opportunities to save costs by altering longstanding patterns of use of medical technology.** It might be desirable to have the new cost-raising but life-extending technologies widely adopted and used and the use of many existing ineffective technologies substantially reduced. The issue for the remainder of this report is how Medicare policy can be structured to bring about the most cost-effective use of both new and existing medical technologies.

Part Two

4.
A Framework for Change

> No great improvements in the lot of mankind are possible, until a great change takes place in the fundamental constitution of their modes of thought.
>
> *John Stuart Mill*

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4.

A Framework for Change

INTRODUCTION

The following chapters examine policies that have been or could be used to restrain the costs of medical technologies in the Medicare program. Several points underlie the analyses in these chapters.

First, the impact of medical technologies on the costs of medical care should not be assessed in isolation from the effects that such medical technologies have on patient care. The impact of cost-containing measures on quality and access is one of the more difficult policy issues to be faced, because the Medicare program was instituted on a payment basis that had few controls on costs. Now that costs are a primary concern of Federal policymakers, some restrictions on quality and access are likely to occur. Nevertheless, there is substantial evidence to suggest that inappropriate use of medical technology is common and raises costs without improving quality of care.

Methods of controlling the costs of medical technologies can vary widely and have varying impacts. Direct methods, for example, are methods that are intended to control the use of specific medical technologies on a technology-by-technology basis. Such methods could be used: 1) to control the actual adoption or use of particular technologies, as in the coverage process that assesses specific technologies before they are approved for payment; or 2) to provide information on the costs of technologies so that payment for their use could be more reasonably related to their costs. Indirect methods include methods that use the payment mechanism to provide broad incentives to medical care providers not to overutilize medical technologies and to make patients more cost conscious in their use of medical services. Indirect methods are now considered the major means through which long-term cost-containment objectives might be achieved. Particularly when used in conjunction with indirect methods, however, some direct methods, such as review of capital spending, utilization review, and some other types of technology assessment activities, may also be valuable.

Second, there are interactions between Medicare and the rest of the U.S. health care system. Because of its size and scope, the Medicare program's policies and procedures affect all aspects of health care delivery, including financing, administration, organization, and personnel. Furthermore, the program affects the content and costs of health care by its influence on the development, adoption, and use of medical technology. Medicare's leverage in the health care system is partly due to the fact that Medicare alone finances over one-third of the country's hospital care, the setting where technology use is concentrated (15). It is also partly due to the fact that other third-party payers often follow Medicare's example.

Nevertheless, it is important to keep in mind that the Medicare program is only one of many public and private institutions that have an influence on the development and diffusion of medical technology. Other important influences are the Food and Drug Administration, National Institutes of Health, manufacturers of drugs and medical devices, hospitals, private health insurers, and professional medical societies. Thus, for example, the leverage of using Medicare-specific payment policies to influence the development and diffusion of medical technology may be limited.

Third, because of spillover effects from one part of Medicare to another, policy mechanisms involving only one part of the Medicare program may have serious limitations in terms of containing costs or affecting the adoption and use of technology. Medicare's hospital payment system based on Diagnosis Related Groups (DRGs), for example, excludes physician services and outpatient care. These exclusions provide financial incentives for the shifting of technologies and costs out of inpatient hospital settings, while leaving physicians' incentives to use medical technology unaffected. Any cost-containment effort must take into account the fact that physicians play a central role in determining what services are provided to patients, both in hospital settings and in nonhospital settings. Most—if not all—cost-containment strategies depend on the ultimate influence of physicians for their success. Cost-containment strategies can be targeted directly at physicians—although such strategies are regarded by most observers as short-term and inadequate approaches—or they can be directed at the practice of medicine through changes in the organizational and financial arrangements under which physicians provide care. For the success of strategies that depend on incentives rather than on direct regulation, it is essential that physicians believe that the incentives are advantageous.

Fourth, the social and political climate today is quite different from that in 1965, and now that Medicare's goal of improving access to health care for the Nation's elderly has been largely achieved, the primary focus of policymakers is on containing Medicare costs. The intent of the original Medicare law (Public Law 89-97) was to increase elderly persons' access, by removing financial barriers, to mainstream medical services, particularly to needed hospitalization (318). The concern about access to medical services was also prominent when disabled persons and those with end-stage renal disease were added to the list of eligible beneficiaries. There was far less concern about the cost of the services than there was about the problems of access, primarily because there was little reason to be concerned. Early principles in addition to improving access included assuring beneficiaries freedom of choice of providers and not interfering in the practice of medicine. Unfortunately, Medicare's adherence to these original principles has contributed to the current cost crisis. Today, in part because the original goals have been largely—though certainly not entirely—attained, the overriding goal for policymakers is to solve the problem of controlling Medicare costs. The challenge is to achieve that goal without diminishing past success.

The aforementioned points are closely intertwined. The relationship between cost containment and its effects on quality and access to medical care is but one example. Equally problematic is the widely held belief that specific policies that could be implemented in the short-term and directed at specific segments of the health care system will provide only temporary relief in medical care cost inflation. On the other hand, long-term success is increasingly dependent on broad but still untested ideas of the kinds of strategies (e.g., "competitive" systems, alternative delivery sites and organizations) that could lead to adequate cost containment. One fundamental dilemma, therefore, is whether policymakers can be precise about cost-containment processes for which the desired outcomes are quite limited, while still exploring the kinds of processes that would lead to the desired long-term or broader cost-containment outcomes.

ORGANIZATION OF THE FOLLOWING CHAPTERS

Chapter 5 examines the potential of linking Medicare's technology-specific coverage policy with technology assessment activities as a means of influencing the adoption and use of specific medical technologies for the ultimate purpose of containing Medicare program costs. In the past few years, assessment of the health effects—i.e., safety and efficacy—of some technologies has become part of the process of arriving at coverage decisions. Two current issues are whether costs should be considered in Medicare coverage decisions and whether coverage of new technologies should be limited to specific sites and providers. This chapter provides information on the Medicare coverage process and technology assessment as practiced in the public and private sectors, and analyzes the strengths and limitations of the current coverage process, technology assessments, and possible linkages between the two processes. It also discusses the role of coverage policy and technology assessment under Medicare's DRG hospital payment system.

Chapter 6 discusses the implications of the DRG hospital payment system[1] for the adoption and use of medical technologies. These implications are varied and to some extent unknown. Much will depend on the way in which the system is implemented and the refinements that will follow. DRG payment levels, especially relative to the speed with which hospitals can reduce costs, will have a major effect on the ability of hospitals to adopt new medical technologies. The way in which capital is paid for will also be an important influence in determining how much and what kinds of new technologies are adopted. Chapter 6 also includes a discussion of alternative approaches to hospital payment and of the implications of these approaches for medical technology.

Chapter 7 describes the Medicare physician payment system and analyzes the impact of proposals to limit physician payment or increasing beneficiary cost-sharing under Part B on medical technology adoption and use. Physicians determine the amount of medical services provided and decide when patients need to be hospitalized, discharged, or provided other types of institutional and noninstitutional care. This chapter examines evidence of excessive use of technologies and methods of enhancing cost consciousness among physicians. Such methods include programs to help ensure appropriate technology use by physicians that might be incorporated in the Medicare program. For example, the law authorizing DRGs also puts into place a mechanism for quality assurance and utilization review by requiring hospitals to contract with regional peer review organizations.

Except for the imposition of minor restraints on the rate of increase of payment levels, Medicare's charge-based method of payment for physicians' services under Part B has been little changed since 1966. This method provides financial incentives to physicians for increased technology use by the way that fees are set and by the coding system used. The achievement of the cost-containment objectives of the DRG-based payment system for hospital services could be partially impeded through movement of some technologies and services out of the hospital setting. For that reason, the law establishing the DRG system requires that data necessary to compute the amount of inpatient physician charges based on DRGs be collected and that the Department of Health and Human Services report to Congress on the prospects of including physicians in DRG payment. The possibility that changes in Medicare payment for physicians' services may lower beneficiaries' access to medical care is also examined, principally through an analysis of the implications of changing physician assignment policy in the Medicare program.

Chapter 8 explores mechanisms other than hospital or physician payment that Medicare could use to foster the appropriate adoption and use of medical technology. These include stimulating competition among providers of health care by encouraging the development of alternative sites and organizations of care such as health maintenance organizations, home health care, and ambulatory surgical centers, and the use of vouchers and other methods.

Examination of these four areas—current Medicare coverage policy and related technology assessment activities, changes in hospital payment, changes in physician payment, and other methods to encourage the appropriate adoption and use of medical technology—lead to the final chapter of this report. Thus, chapter 9 presents OTA's conclusions and policy options.

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[1] The recent changes in Medicare's hospital payment system established by the Social Security Amendments of 1983 (Public Law 98-21) are more extensively discussed in OTA's July 1983 technical memorandum *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343).

5.

Specific Medical Technologies: Linking Coverage Policy and Technology Assessment To Contain Costs

Indeed, what is there that does not appear marvelous when it comes to our knowledge for the first time?

Pliny the Elder

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5.

Specific Medical Technologies: Linking Coverage Policy and Technology Assessment To Contain Costs

INTRODUCTION

The introduction of a new technology sometimes has large and unanticipated impacts on Medicare expenditures (see ch. 3). The extent of impact depends on whether Medicare chooses to cover (i.e., pay for) the technology, and, if it chooses to cover it, to specify the conditions of its use. Coverage policy, i.e., policy that governs the eligibility of services (technologies) for payment, has been a significant factor in hospitals' decisions regarding the *purchase* of expensive, visible medical technology (24,289). The relationship between coverage policy and adoption of other kinds of medical technology or the *use* of any medical technology remains speculative.

Title XVIII of the Social Security Act specifies broad, general categories of medical and health services (e.g., hospital services and physicians' services) and some specific items (e.g., home dialysis supplies, pneumococcal vaccine) that the Medicare program will cover (see ch. 2). It also lists a number of specific services and items that the program will not cover. For the most part, however, decisions about which technologies Medicare will pay for are made at the national level by the Health Care Financing Administration (HCFA) or at the local level by Medicare contractors.

In the past few years, rapid technological development has led to an increasing need for decisions by Medicare and other third-party payers about the coverage of specific technologies. Many coverage decisions are based on an assessment of the health effects of the particular technology. For the most part, these assessments are not rigorous. Indeed, it is estimated that only 10 to 20 percent of technologies used in medical practice have been shown to be efficacious by controlled trials (341). Evaluation of the nonmedical effects, for example, economic and social effects, of specific technologies is usually not part of an assessment for coverage purposes.

This chapter discusses the possibility of refining Medicare's coverage policy, for example, by using appropriate technology assessments, as a means of influencing the diffusion of medical technology. Changes in Medicare's coverage policy for specific technologies may provide an incremental approach to controlling Medicare costs.

DEFINITIONS

Coverage is generally defined as "the guarantee against specific losses provided under the terms of an insurance policy." The term is frequently used interchangeably with benefits or protection. Coverage also means "the extent of insurance offered by a policy" (335). Insurance plans (including Medicare) specify, to varying degrees of precision, the benefits they will pay for. Thus, coverage refers both to the broad categories of benefits specified in the law or in a plan as well as to the specific services actually provided and paid for. In the Medicare program, coverage is distinguished from payment or reimbursement: coverage refers to benefits available to eligible beneficiaries, and payment refers to the amount and methods of payment for covered services (434).

". . . [T]echnology assessment is simply a broader form of policy research than is commonly conducted. The goal of technology assessment, as of all policy research, is to provide decisionmakers with information on policy alternatives, such as allocation of research and development funds, formulation of regulations, or development of legislation" (23). A comprehensive assessment examines the technical, economic, social, and legal consequences of technological applications. A less comprehensive assessment of a medical technology may focus only on the health effects of the technology. The typical meaning of the term "technology assessment" in health policy today is an evaluation of a technology's efficacy and safety and sometimes costs.

MEDICARE COVERAGE

The basis for decisions by HCFA or Medicare contractors regarding the coverage status of medical technologies not otherwise specifically mentioned in Title XVIII of the Social Security Act is Section 1862. Section 1862, among other things, prohibits payment by Medicare for any expenses incurred for items and services which are not "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. . . ." The provision applies "notwithstanding any other provisions" of the title.

Coverage policy for specific technologies is expressed in the development, issuance, and implementation of coverage decisions. Such policy is made in light of Medicare's twin principles of not interfering with the practice of medicine and of assuring beneficiaries a free choice of providers. For the most part, questions regarding Medicare coverage status arise with respect to new technologies or new applications of covered technologies, although occasionally, the coverage status of covered, established technologies is reexamined. The focus of this chapter is on the Medicare coverage process for new technologies and new uses of covered technologies.[1]

There is a basic contradiction between Medicare's stated intention of not interfering with the practice of medicine and the delivery of health care and its coverage policy that judges technologies to be used in medical practice. A decentralized approach to the coverage process attempts to minimize the contradiction by accepting the premise that medical practice varies from one geographic area to another.

Some Medicare coverage decisions for specific technologies are made at the national level by HCFA's central office. Most of the decisions, however, are made by Medicare contractors who perform the Medicare program's claims processing and payment function under the policy and operational guidance of HCFA. Medicare contractors, called intermediaries and carriers, are either Blue Cross/Blue Shield plans or commercial insurers. On the U.S. mainland, 84 intermediaries administer Part A (institutional services) of the Medicare program, and 61 carriers administer Part B (physicians services) (see app. E).[2] HCFA's 10 regional offices assist contractors with coverage decisions and transmit information between HCFA's central office and Medicare contractors.

Because of the general language of Section 1862 and the absence of regulations that implement the section, **HCFA officials and Medicare contractors alike have had considerable latitude in determining which technologies are to be covered for reimbursement.**

Medicare coverage policy is continuously evolving and is developed and implemented in a decentralized manner. National policy has developed largely as a result of questions from individual contractors about whether they should pay for specific technologies (366,435). HCFA informs contractors about the coverage status of some specific technologies through transmittal letters and a Medicare manual. However, HCFA's coverage instructions have no standing in law or regulation, so the contractors' compliance is essentially voluntary (366).

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[1] The term "new technologies" henceforth refers to both new technologies and new uses of established technologies.

[2] There are two governmental bodies that perform similar functions: the Office of Direct Reimbursement and the Group Health Plan Operations Staff in the Bureau of Program Operations. HCFA is moving to contract out the intermediary functions of the Office of Direct Reimbursement to regional intermediaries.

There is variation among Medicare contractors in a number of areas (54,143,353, and app. E):

- their identification of specific medical technologies that are not covered,
- their decisions about the coverage of specific technologies, and
- their implementation of national coverage decisions made by HCFA.

Because of the variation among contractors, some technologies may be covered and paid for in one geographic area and not in another. There is no national or local listing of procedures that are not covered (163).

Part of the variation stems from the absence of precise definition of "reasonable and necessary." There are, however, specific criteria that are applied to a technology to determine if the technology meets the broad statutory language of "reasonable and necessary." These criteria are found in program instructions prepared by HCFA and sent to the Medicare contractors. The technology must be (435):

- generally accepted as safe and effective,
- not experimental,
- medically necessary, and
- provided according to accepted standards of medical practice in an appropriate setting.

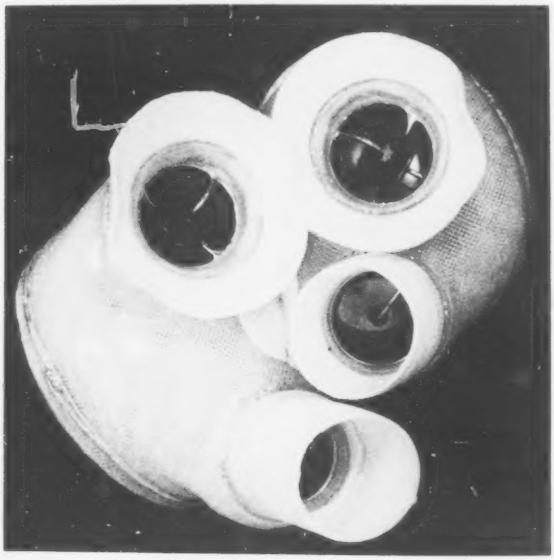


Photo credit: The University of Utah Medical Center

The Jarvik 7 artificial heart is an example of an experimental technology that has not been approved for Medicare coverage

Of particular interest to cost-containment efforts is that Medicare's policy is to exclude the explicit consideration of cost information in making coverage decisions.[3] At one point, in the context of a proposed regulation to define the meaning of "reasonable and necessary" more clearly, HCFA debated establishing criteria and standards for taking nonmedical factors, including economic factors, into account in making coverage determinations (268). Active consideration ended with the change in administration in 1981.

Another important point is that Medicare has refrained from a policy of limiting coverage of particular technologies to restricted circumstances (e.g., to institutions offering specific services or having specialized equipment, or to physicians with specific skills). Although the notion of limiting coverage has gained importance with the increasing development of sophisticated technologies that require particular expertise, the dictum of refraining from interfering with medical practice appears to be foremost.[4]

On the other hand, Medicare does limit coverage of some technologies to appropriate medical conditions. Thus, for example, in August 1981, HCFA announced the coverage of specific types of therapeutic apheresis for three conditions but denied coverage of apheresis for other indications. Three additional disease indications were added in 1983 (349).

---

[3] A dramatic exception was heart transplantation. As a result of the controversial nature of the technology, including economic, social, ethical, legal, and moral concerns, the evaluation and subsequent coverage decision has been delayed for additional research evidence, including cost-effectiveness data (107).

[4] There appears to be a lessening of adherence to the concept of not covering technologies for limited situations. Although no policy change has been announced, the coverage of apheresis, which became effective on Jan. 31, 1983, is limited to the performance of apheresis only in the inpatient or outpatient hospital setting (74). Also, in July 1983, HCFA released coverage instructions to Medicare contractors that limits payment for a technology to its use in a specific setting and by specific providers. Closed loop blood glucose control devices will be paid for only if used in a hospital inpatient setting under the direction of specially trained medical personnel for insulin dependent diabetes during crisis intervention (383).

The Coverage Process

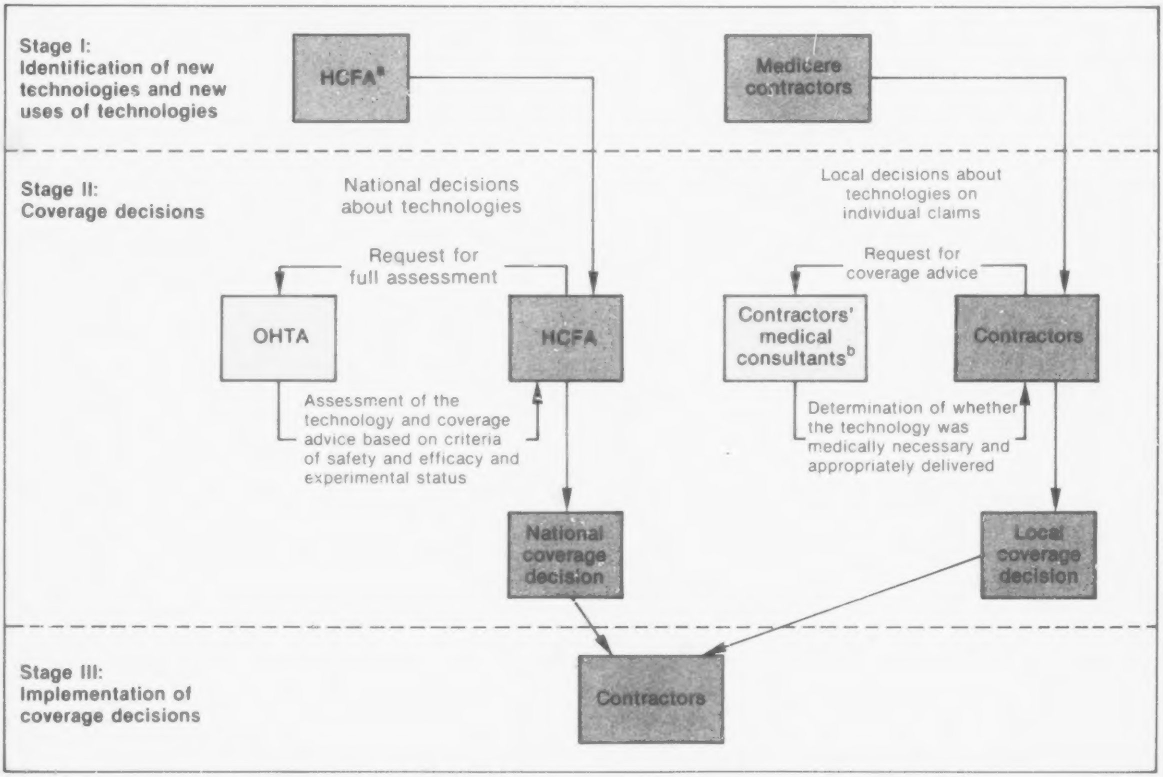
Medicare's coverage process is depicted in figure 2 and described in detail below. The coverage process is generally (except for details) the same at the national and contractor levels. First, a new technology or new use of a covered technology is identified. Second, a decision is made about covering the identified technology for Medicare payment. The third and final step of the process, implementing the coverage decision, is mainly the contractors' responsibility.

Identification of New Technologies and New Uses of Technologies

The identification of a new technology for a coverage determination may be done by a Medicare contractor, by one of HCFA's 10 regional offices, or by HCFA's central office. Medicare contractors use general guidelines distributed by HCFA. In the last few years, the guidelines have been made broader and more general. HCFA assumes that Medicare contractors are familiar with medical and hospital practices and thus relies on the contractors' knowledge and experience (173).

Medicare contractors use various methods for identifying new technologies. In the recent past, claims review appeared to be the primary method

Figure 2.—Model of Medicare's Coverage Process for Individual Medical Technologies


Stage I:
Identification of new technologies and new uses of technologies
HCFA[a]
Medicare contractors
Stage II:
Coverage decisions
National decisions about technologies
Local decisions about technologies on individual claims
Request for full assessment
Request for coverage advice
OHTA
HCFA
Contractors' medical consultants[b]
Contractors
Assessment of the technology and coverage advice based on criteria of safety and efficacy and experimental status
Determination of whether the technology was medically necessary and appropriately delivered
National coverage decision
Local coverage decision
Stage III:
Implementation of coverage decisions
Contractors

[a] Sources of coverage questions submitted to HCFA are identified in table 15.

[b] Sources of assistance for Medicare contractors' medical consultants in making coverage decisions are identified in table 14.

SOURCE: Office of Technology Assessment.

for identifying uncovered technologies. A 1983 survey of Medicare contractors, the results of which are presented in appendix E, however, found that most contractors learn about new technologies for which coverage questions might be raised through inquiries from providers and manufacturers prior to the submission of claims. Other important sources of information about new technologies are the drug and device approval lists from the Food and Drug Administration (FDA) and announcements from HCFA. Some contractors keep informed about new developments through the medical research literature, or contacts with medical specialists, or supplier demonstrations and mailings.

The claims form, despite the use of other tools, is still an essential, albeit imperfect, identification tool. The claims review process, described in appendix E, was established for paying bills, not for identifying technologies. Furthermore, under HCFA's current allowances for administrative costs, Medicare contractors are financially constrained to limit their review process.

The claims form for hospital services under Medicare's traditional cost-based hospital reimbursement method[5] is not designed to identify new technologies. This claims form groups services under broad headings, such as radiology and pathology, and provides little information about specific technologies (291). Furthermore, under cost-based reimbursement since 1981, HCFA has required intermediaries to examine only a 20-percent sample of inpatient hospital claims (384).

On the claims form for physician services, a Part B service, the physician is required to supply information about the use of specific surgical and medical technologies. New technologies are recognized by the absence of code numbers, by the presence of codes that are not recognized, or occasionally, by the excess charges for a type of service (54 and app. E). Because of the nature of the claims form and the fact that almost all the forms for physicians' services are reviewed, it is commonly assumed that carriers, the contractors who administer Part B of Medicare, are more likely to identify uncovered technologies from claims forms than are intermediaries. It should be noted, however, that carriers may overlook new technologies because of inefficiencies in the review process and a high number of coding errors. It is also possible for physicians and hospitals to code new procedures under codes for established procedures (54).

Some observers indicate that intermediaries, the contractors who administer Part A, can identify high-cost technologies. If a hospital or other inpatient facility exceeds a set level of expenditure for a particular type of service, the intermediary may examine the medical record and identify an uncovered technology. Intermediaries may compare annual Medicare cost reports (MCRs) from year to year to compare expenditures for groups of services. At times, hospitals have recorded a specific uncovered technology on the MCR, as well (17). On the whole, however, specific technologies are not identified on the MCR, which is reviewed for financial purposes and not technological use.

Most Medicare contractors in the 1983 survey presented in appendix E were reasonably well satisfied with existing methods for identifying new technologies and reported that this was not a serious problem for them. Some contractors mentioned a need for greater cooperation between national medical and insurance associations and governmental agencies in supplying information about new technologies to facilitate the identification process.

Coverage Decisions

Coverage decisions are made by Medicare contractors and by HCFA's central office. Local decisionmaking is informal and has no standing in law or regulation. National coverage decisions are made informally, as well, and the decisionmaking process has no regulatory status (114).

Medicare contractors, advised by their medical consultants, decide most of the coverage issues that are raised in their own geographic area. Indeed, less than 1 percent of the 250 million claims processed in fiscal year 1983 were sent to HCFA's central office for coverage decisions (88). Most questions are not of national interest. Furthermore, the contractors view their function as paying claims as quickly as possible and are disturbed by the delays in referring questions centrally (366). Although a special office dealing with coverage issues, the Office of Coverage Policy in the Bureau of Eligibility, Reimbursement, and Coverage, was established in HCFA as a result of a 1979 memorandum, it does not appear that the pattern of decisionmaking has changed significantly (61).

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[5] The claims form and the claims review process under Medicare's DRG payment method are not sufficiently established for comment at this time. As noted in ch. 2, some hospitals and some hospital units will continue to be paid under Medicare's cost-based reimbursement method.

When considering coverage questions, most medical consultants to contractors appear to rely on similar sources of information, including HCFA regional offices, colleagues in other insurance companies or Blue Cross/Blue Shield plans, and State or national medical or specialty societies (see table 14).

Most of the questions raised during claims review pertain to whether a particular technology was medically necessary in the case under review and whether the technology was furnished in an appropriate manner and setting. Sometimes, however, the broader issue of general coverage arises, i.e., whether the technology should be covered under any circumstance. National coverage questions are to be referred to HCFA's central office (435). Nonetheless some contractors' medical consultants make decisions about national coverage issues.

Because of variation in the types of coverage questions that Medicare contractors consider and their decisions about any one question, the specific package of covered services varies from contractor to contractor. The 1983 survey of Medicare contractors found variation in coverage decisions made by medical consultants of Medicare contractors (see app. E).

In an attempt to modify differences and inconsistencies in Medicare benefits in its region, HCFA's Boston Regional Office issued a bulletin in 1978 to Medicare intermediaries and carriers describing a "general approach that should be taken with respect to determining coverage of new or unusual procedures which the Medicare Bureau either has not categorized as covered or uncovered, or on which [it has] not advised [them] that a national coverage policy decision is currently pending" (388). The bulletin emphasized the expeditious use of medical consultants and suggested the referral of general issues to HCFA's regional and central offices. Although the guidelines described in the bulletin are not enforceable, the Boston Regional Office believes that contractors in the Boston region have improved their coverage process and that the improvement has resulted in greater consistency in covered benefits in the area (73).

HCFA's central office issued a similar directive to contractors nationwide in 1981 concerning its expectation that contractors refer coverage issues of national interest to the office (384). However, referral is not required by statute or regulation, and HCFA's request is not uniformly honored.

The current locus for coverage questions within HCFA is the Office of Coverage Policy. If medical advice is needed in order to arrive at a coverage decision, the question is presented to HCFA's Physician Panel. The panel may then request tech-

Table 14.—Sources of Information Used by Medical Consultants in Making Coverage Decisions

Source	Percent of consultants using source	
	Yes	No
Colleagues in another insurance company or Blue Cross/Blue Shield Association plan	78.6	21.4
HCFA regional office	87.5	12.5
University medical center	44.6	55.4
PSRO (PRO)	26.9	73.1
National insurance association	37.5	62.5
State or national medical or specialty association	75.0	25.0
Drug or device manufacturer	53.6	46.4
Other	51.0	49.0

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

nology evaluations from the Office of Health Technology Assessment (OHTA),[6] which has taken over the coverage responsibilities of its predecessor, the National Center for Health Care Technology (NCHCT) (386).

After conducting an assessment on the safety, efficacy, and clinical effectiveness of a technology (399), OHTA may recommend to HCFA that a technology not be covered by Medicare or that it be covered with or without restrictions. The coverage decision is made by HCFA, which subsequently notifies its contractors and State Medicaid agencies. In almost all cases, HCFA accepts OHTA's recommendation.

In the late 1960's and throughout most of the 1970's, the vast majority of coverage questions received at HCFA's central office were submitted by the regional offices (381). From 1978 to 1982, however, the proportion of questions submitted by the regional offices declined (see table 15). After 1979, other parties, particularly manufacturers, increased their participation in the coverage process. In 1978 and 1979, there were no direct inquiries from drug or device manufacturers, but during 1981, 25 percent of the coverage questions submitted to HCFA's central office were from producers of medical technologies (see table

Table 15.—Sources of Coverage Questions Submitted to HCFA's Central Office

	Inquiry source—by source, year, number, and percentage				
Source	1978	1979	1980	1981	1982 (through November)
HCFA regional office	19 (61.3%)	9 (32.1%)	19 (59.4%)	11 (34.6%)	7 (24.1%)
Manufacturers			1 (3.1%)	13 (25.0%)	3 (10.3%)
Hospitals/clinics	1 (3.2%)	1 (3.6%)		1 (1.9%)	1 (3.4%)
Physicians	1 (3.2%)	4 (14.3%)		5 (9.6%)	3 (10.3%)
Medical schools		2 (7.1%)			1 (3.4%)
Legislatures	1 (3.2%)			1 (1.9%)	1 (3.4%)
Professional societies	2 (6.5%)	5 (17.9%)	2 (6.3%)	2 (3.8%)	
Blue Cross		1 (3.6%)	2 (6.3%)	2 (3.8%)	1 (3.4%)
Blue Shield			2 (6.3%)		
Blue Cross/Blue Shield					1 (3.4%)
Private insurance			1 (3.1%)	2 (3.8%)	
Health Care Financing Administration		5[a] (17.9%)	1 (3.1%)	2 3.8%)	7 (24.1%)
Public Health Service			2 (6.3%)	2 (3.8%)	2 (6.9%)
Attorneys			1 (3.7%)		1 (3.4%)
Information not available	7 (22.6%)	1 (3.6%)	1 (3.1%)	4 (7.7%)	2 (6.9%)
Total	31 (100%)	28 (100%)	32 (100%)	52 (98.2%)	29 (99.6%)

[a] Four of these questions arose from the Blue Cross/Blue Shield Medical Necessity Project

Data sources: Health Care Financing Administration, internal data sheets and HCFA staff

SOURCE: Office of Technology Assessment

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[6] OHTA is located in the National Center for Health Services Research in the Public Health Service. It should not be confused with the congressional Office of Technology Assessment (OTA).

15). The now defunct NCHCT may have been partially responsible for the increase in manufacturers' questions, because it referred the manufacturers' inquiries it received to HCFA (258). HCFA files show that questions about coverage for a particular drug or device in some cases were submitted at approximately the same time by both the manufacturer and an interested provider.

The Health Industry Manufacturers Association (HIMA) has spent considerable effort in educating its members about health coverage and reimbursement (385). Such attempts may be a significant factor in stimulating manufacturers' interest in requesting coverage. For a few years, HIMA encouraged manufacturers to go directly to HCFA's central office to obtain coverage for their products and service. In the past year or two, HIMA has suggested that its members contact contractors, particularly carriers, because of its perception that the time required for making and releasing coverage decisions and the number of denials at the national level has increased. The decline in direct inquiries for coverage to HCFA's central office—from 25 percent of the total number of inquiries in 1981 to 10.3 percent in 1982—may reflect the change in strategy.

Implementation of National Coverage Decisions

There is no formal mechanism for implementing Medicare coverage decisions made at the national level. For the most part, HCFA's function is limited to disseminating the decision to contractors and providers through various sources, including HCFA's regional offices, instruction manuals, and transmittal letters. Government involvement is largely confined to cases of fraud and abuse.

As noted earlier, Medicare contractors have no legal responsibility to adhere to the coverage decisions made by HCFA's central office. The manual instructions, including the coverage index appendix, and the letters to the contractors are usually considered interpretive rules and thus not legally enforceable (366).

Nonetheless, the contractors' claims review process is an unofficial and limited means of implementing national coverage decisions. Claims requesting payment for noncovered services and claims with incompatible diagnostic and procedure codes are usually referred to the contractors' nurse reviewers, and if necessary, to physician consultants (see app. E). However, no distinction can be made between those technologies that are not covered because a coverage question has not been raised and those technologies that are not covered because they have been denied coverage.

Until recently, little empirical evidence was available about the contractors' role in implementing national coverage decisions. A recent survey of the implementation of Medicare nursing home benefits by intermediaries found the use of skilled nursing facilities by Medicare beneficiaries to vary considerably from one State to another, a variation that reflected wide differences in the interpretation and administration of rules governing nursing home coverage (314). The researchers concluded that the wide variation was due to the complexity of Medicare coverage rules and to Medicare's decentralized administration.

The 1983 survey of Medicare contractors mentioned above (see app. E) came to somewhat similar conclusions. The survey found considerable variation in the implementation of HCFA transmittals among contractors. This variation was apparently not related to certain characteristics of the contractors, including insurance type (Blue Cross/Blue Shield or commercial), geographic location, or claims volume.

Part of the variation in implementation of coverage decisions appears to result from what is perceived as a lack of clarity in HCFA's coverage instructions. Fifty-five percent of the Medicare contractors surveyed in 1983 said they were always or almost always able to implement HCFA transmittals concerning the coverage status of particular technologies without obtaining further interpretation. However, 45 percent of the contractors reported that the transmittals sometimes, rarely, or never could be implemented without further interpretation (app. E).

Some contractors also indicated they were not given sufficient time for implementing national coverage decisions, sufficient information about technologies undergoing assessment, or revisions in coverage policy. As noted earlier, HCFA's current policy is based on the premise that contractors' have sufficient knowledge and expertise to allow for general coverage instructions. Nonetheless, some contractors are not content with the policy and said that the content of HCFA's instructions could be improved by including more specific criteria and by eliminating ambiguous terms, such as "chronic" and "necessary" (app. E).

The 1983 survey of Medicare contractors also examined decisionmaking by Medicare contractors regarding the coverage of specific technologies.[7] It found various degrees of variation among contractors in their coverage of technologies included in the survey (app. E).

The study technologies were categorized according to HCFA coverage status: 1) explicit coverage by HCFA, 2) HCFA coverage with qualifications, 3) no explicit HCFA policy, 4) implicit denial of coverage by HCFA, and 5) explicit denial of coverage by HCFA (see table 16). The variation in coverage was least in instances in which HCFA had explicitly approved coverage. Table 16 shows that some contractors covered technologies in this category with qualifications when

Table 16.—Reported Coverage Decisions by Medicare Contractors

Technology/HCFA coverage policy	Decisions/policy of contractors Covered	Not covered	Covered with qualifications	Refer for advice
HCFA explicitly covers:				
Lens implant	98.2%	—	—	1.8%
Pacemaker: chronic second degree AV block	70.9	—	20.0%	9.1
PTCA: single vessel procedure	61.1	3.7%	25.9	9.3
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	8.0
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7
HFCA covers with qualifications:				
Home blood glucose monitor	11.8	7.8	72.5	7.8
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8
PUVA: psoriasis	38.5	5.8	50.0	5.8
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	15.4
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	19.2
External insulin infusion pump	10.6	46.8	27.7	14.9
No explicit HCFA policy—contractor decides (local option):				
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	13.2
Streptokinase at cardiac catheterization: AMI	30.2	45.3	15.1	9.4
Chemonucleolysis: herniated disc	64.0	10.0	14.0	12.0
HCFA denies, but not explicitly:				
Biofeedback: intractable pain	9.3	55.6	31.5	3.7
PTCA: two or more coronary arteries	19.2	51.9	19.2	9.6
Apheresis: systemic lupus erythymatosis	18.0	60.0	14.0	8.0
HCFA explicitly denies:				
Chelation therapy: atherosclerosis	—	87.0	3.7	9.3
Pacemaker: sinus bradycardia without symptoms	13.0	44.0	29.6	13.0
24-hour blood pressure monitoring: automatic (policy effective 7/83)	8.3	52.1	27.1	12.5
24-hour blood pressure monitoring: semiautomatic or patient activated	4.2	77.1	8.3	10.4
EEG monitoring: open heart surgery	15.4	71.2	9.6	3.8
Topical oxygen therapy: decubitus ulcers	7.8	86.3	5.9	—

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

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[7] The study was exploratory and descriptive, with many methodological limitations (see app. E). The questions about individual technologies were intended to ascertain what the contractor's policies generally were with respect to coverage. The telephone interviewers/researchers did not use the word "implementation" and did not check on the degree to which contractors adhere to HCFA policy guidelines. Indeed, most coverage issuances allow for variation, depending on further investigation of the claim and the circumstances of the individual patient. Variation among contractors was expected, because the coverage status of the technologies included in the survey are difficult to determine. Nonetheless, examining the contractors' coverage decisionmaking process at one point in time does give some indication of the contractors' compliance with national coverage decisionmaking.

there were no qualifications imposed by HCFA. However, this practice reflects not a lack of compliance with HCFA's policy, but rather caution on the part of contractors to assure that HCFA's criteria were met.

From table 16, it would appear that there is significant variation among the technologies in the second category, i.e., those that HCFA covers with qualifications. However, most of the variation exists because of the three infusion device technologies included in the category. When the survey was conducted, policies concerning infusion devices were undergoing review, and there was considerable uncertainty among contractors as to the current coverage status of the devices. If one eliminates the infusion device therapies from the category, the variation decreases considerably (app. E).

Coverage decisions on technologies for which HCFA had explicitly denied coverage showed more variation than one might expect. That may be an artifact of the particular technologies included in the survey or may indicate a reluctance on the part of the contractors surveyed to flatly deny coverage without further investigation of the claim. Variation is, predictably, much greater for technologies for which contractors have made local coverage decisions and those for which HCFA intends to be denied but for which there is no explicitly stated policy (app. E).

In most instances, the majority of the contractors complied with HCFA's directives. Yet compliance was sufficiently diverse among the contractors as to result in variation. In general, the variation can be attributed to differing impressions on the part of the contractors about the coverage status of the particular technology, which may result from unclear or complex HCFA coverage policy, a change in policy, or a policy in the formation stage; the inherent complexity of clinical medicine and the difficulty of precisely matching a claim for a specific patient with a general policy written to cover many patients; and limitations of the study—e.g., the findings reflect responses to a hypothetical situation at one point in time.

Coverage Policy Under Medicare's DRG Hospital Payment System

In October 1983, following enactment of Public Law 98-21, Medicare began phasing in prospective hospital payment system using Diagnosis Related Groups (DRGs) as the case-mix measure.[8] Federal regulations (114) state:

> . . . prospective payment legislation did not change Medicare coverage or eligibility rules currently in effect . . . as a result, national coverage rules continue to be applicable. These rules will continue to be applied by intermediaries with assistance from PROs [utilization and quality control peer review organizations] and PSROs [professional standards review organizations] where appropriate.

DRG payment is not applicable to psychiatric hospitals, rehabilitative hospitals, pediatric hospitals, long-term hospitals, psychiatric and rehabilitative units operating as distinct parts of acute care hospitals, and physician services—provided in or out of the hospital. Thus, Medicare coverage for these institutions and services remains unaffected by the change in payment method.

Although the regulations require that coverage rules remain, the structure of DRGs places little emphasis on individual technologies. Thus, under DRG payment for inpatient services, HCFA will rarely be able to discern the use of particular technologies. Multiple combinations of drugs, devices, and procedures are possible within almost all DRG categories; specific technologies are not easily evident from DRG classification. For the most part, only a few of the 470 DRGs mention particular technologies. With few exceptions, specific drugs and medical devices were not variables in the construction of DRGs as a patient classification system. Drugs are not specified in any of the 470 DRGs, and only one medical device, the pacemaker, is specified as or part of a DRG. Although the first major subdivision within most of the 23 major diagnostic categories (MDCs) of the classification system is "the presence or absence of an operating room procedure" (389), the specific type or types of surgical procedures are not explicitly mentioned in most DRGs. Except for a few, such as heart transplantation surgery (DRG 103), coronary bypass (DRGs 106 and 107), and perhaps arthroscopy (DRG 232), the DRGs that describe most surgical procedures, e.g., pelvic procedure (DRG 334), are so general that many different surgical techniques could be used to carry them out (32).

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[8] See chs. 2 and 6 for further discussion of the DRG hospital payment method.

The inability to identify the use of particular technologies under Medicare's DRG hospital payment method does not differ markedly from the situation under Medicare's previous retrospective cost-based hospital payment method. As noted above, inpatient hospital claims forms and MCRs under cost-based reimbursement do not specify the use of individual technologies.

There are, however, several ways under DRG hospital payment to identify uncovered individual technologies that may raise hospitals' costs. For example, outlier cases, cases involving either an extremely long length of stay (LOS outlier) or extraordinarily high costs (cost outlier) when compared to most discharges in the same DRG, will be reviewed in their entirety for noncovered or medically unnecessary or inappropriate days or services (114). Outlier cases may occur precisely because new and costly technologies were used in the care of the patient. If a new technology is not covered, outlier payments will be denied.

New technologies will also be recognized during the process of adjusting DRG rates for all hospitals. **Indeed, updating DRG weights appears to offer the most significant opportunity for identifying new technologies for coverage purposes.** The decision to adjust DRG rates can therefore be considered a quasi-coverage decision itself.

Changes in DRG relative weights or prices will be made, in part, to reflect technological change. Because the DRG rate adjustment process includes identification of new technologies, it is reasonable that some of the techniques, including technology assessments, used in the process will be similar to those used for supporting coverage decisions. Indeed, the Prospective Payment Assessment Commission (ProPAC) has been given broad powers to assess medical technology and the appropriateness of medical practice patterns in developing its recommendations for DRG rates. ProPAC's role is only advisory; HCFA makes the decision concerning the appropriate payment rate for hospital services.

Thus, both the coverage process and the process of adjusting DRG rates share a similar "approval for payment" function. They differ in that a coverage determination focuses on specific technologies, while adjusting DRG payment rates focuses on the larger entity of a diagnostic group, which may include particular technologies. **A more important difference is that the coverage process rarely considers costs, while the DRG rate adjustment process must include cost as an integral issue.** Nonetheless, the technology assessments performed for both processes may be similar. The potential for duplication is not to be ignored. **The processes seem to be sufficiently similar to warrant coordinated Government effort.**

Whether technologies will be subject to a double review of safety and efficacy for payment purposes will depend on the approach chosen to update DRG rates. Irrespective of approach, it is reasonable to assume that hospitals' adoption of cost-raising technologies will be made evident to HCFA for DRG payment and for coverage determinations. However, some approaches to updating DRG rates, such as through outlier cases, would not surface cost-saving technologies. In addition, specific technologies will not be identified on the DRG hospital claims form, so the use by a hospital of a new, uncovered technology that lowers per case costs will not become known to HCFA through hospital claims review. HCFA intends to rely on physician claims and other sources for information to stimulate the initiation of a technology assessment solely for coverage purposes. As in the past, many technologies may go unnoted.

EVALUATING TECHNOLOGIES FOR COVERAGE DECISIONS

Current Activities[9]

Before arriving at coverage decisions, both Medicare contractors and HCFA's central office have medical technologies evaluated. The evaluations performed for contractors by medical consultants are usually informal and have limited influence on the diffusion of medical technologies. The evaluations performed for HCFA's central office affect the diffusion of technologies nationwide. The primary factors considered in such assessments are safety and effectiveness. **Because cost criteria are not included as factors in assessments for Medicare coverage decisions, expensive technologies are eligible for coverage without regard to cost effectiveness.**

At present, the body that is responsible for evaluating the medical and scientific aspects of medical practice for HCFA is NCHCT's successor, OHTA. OHTA responds to HCFA's simple inquiries about the regulatory and research standing of particular technologies by providing information obtained from the responsible Public Health Service (PHS) agency. It also conducts "full" assessments at the request of HCFA with the objective of providing HCFA with the most current and scientifically valid information on which to base coverage decisions.

The OHTA assessment process follows the process established by NCHCT. OHTA reviews the scientific literature and obtains opinions from experts in the public and private sector and then synthesizes the information it receives.

In conducting its evaluations, OHTA uses numerous sources for information.[10] If the evaluation concerns drugs or certain medical devices, prior evaluations by FDA provide some indications of safety and efficacy; for procedures, however, there is no comparable mechanism. For a drug to be covered under Medicare, FDA approval is required. The *use* of drugs, however, is not usually questioned by HCFA. Drugs are covered for payment when provided in an inpatient setting and their use is not monitored by HCFA; hardly any drugs are covered for payment when provided in an outpatient setting.

OHTA's evaluations are confounded by definitional problems. The definitions of safety and effectiveness, for example, differ among Government agencies. Thus, FDA considers a medical device to be effective when, on the basis of well-controlled investigations or other valid scientific evidence, the device is shown to have the effect claimed by the manufacturers under the manufacturer's specified conditions of use (21 U.S.C. 260c(3)). On the other hand, HCFA judges the effectiveness of a medical device in terms of its ability to improve health. Thus, some devices approved by FDA for marketing purposes are not covered by HCFA for payment (435).

There are other definitional problems. Coverage decisions about technologies of national interest are based on criteria of "general acceptance" and "stage of development." If a technology is generally accepted by the medical community as being safe and effective ("general acceptance") and is perceived to have moved beyond experimental status to clinical application (reasonable "stage of development"), then it is considered "reasonable and necessary." However, the terms used in the criteria are not defined precisely.

Applying the criterion of "general acceptance" to a new technology is difficult, because a new technology has usually been used by only a small fraction of the medical community. In such cases, coverage decisions are based on scientific evidence and professional judgment of safety and effectiveness. Yet standards for adequate proof of safety and effectiveness have not been established (435).

The criterion of reasonable "stage of development" also creates problems in evaluating a new technology for coverage. Technologies do not progress neatly from research to development to clinical phases but more often are used simultaneously as research and investigational tools and in medical practice (359). The distinction between an experimental and emerging technology may be arbitrary. Some contend, for example, that Medicare reimbursement was approved for kidney transplantation when the survival rate was less than it is now for liver transplantation, which is not reimbursed (43).

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[9] See app. C for a detailed discussion of the Government and private sector assessment activities.

[10] For a discussion of OHTA's method of evaluating medical technology, see app. C.

Following its evaluation, OHTA sends its assessment and a recommendation based on the assessment to HCFA. The recommendation summarizes the evidence and PHS' conclusions about the safety and clinical effectiveness of the technology under review. The assessment is not made public routinely upon its completion; the recommendation is not released until HCFA has made its decision on the issue (58).

For the most part, OHTA has not explicitly considered cost and cost effectiveness in its evaluations, although the Memorandum of Understanding between HCFA and PHS does not preclude this possibility (410). ProPAC is given powers to assess the cost effectiveness as well as the safety and efficacy of new and existing medical and surgical procedures, but its primary responsibility is to recommend changes in DRG payment rates. Although ProPAC is specifically mandated to assess medical practice in making its recommendations, it is unknown at this time how extensive its assessment activities will be.

In addition to the Federal Government, the private sector is involved in assessing technologies. Insurers and other organizations use technology assessments for coverage and other determinations (e.g., payment, purchasing, and management decisions). Indeed, the present approach to medical technology assessment is characterized by multiple participants from the public and private sectors and by uncoordinated activities (359). The private and nonprofit sectors have increased their involvement in the past 2 years. However, many of the assessments that are conducted are limited to specific organizational objectives and have limited value for national policy decisions. Safety and efficacy are usually used in technology assessments; economic, legal, social, and ethical criteria are sometimes used.

Analytic Methods of Comparing Costs and Benefits

Although evaluating the safety and efficacy of medical technology has protected patients from risky, unproven, and ineffective services (359), the need for evaluation of the economic effects of medical technology is becoming increasingly important as Medicare and health care costs in general continue to escalate.

In theory, the chance of containing Medicare costs through coverage policy would be increased by including not just safety and efficacy criteria but cost and cost-effectiveness criteria in Medicare coverage decisions. The general value of formal analytic techniques for comparing costs and benefits, referred to collectively as cost-effectiveness analysis/cost-benefit analysis (CEA/CBA),[11] in decisionmaking about the use of medical technology was addressed in OTA's 1980 report *The Implications of Cost-Effectiveness Analysis of Medical Technology* (353). That report also identified the methodological strengths and weaknesses of the techniques and the potential for initiating or expanding the use of CEA/CBA in reimbursement coverage programs.

CEA/CBA potentially can be more valuable for decisionmaking under a constrained budget, when tradeoffs have to made directly, than when constraints are nonexistent or very indirect (as in most current reimbursement programs). In neither case, however, would CEA/CBA necessarily function as an effective cost-constraining mechanism or tool. Under a budget system, the budget itself would be the constraining mechanism. Under a nonconstrained system, since no direct tradeoffs are required, no direct limit on expenditures is set. Nevertheless, CEA/CBA might change the mix of expenditures (353). Medicare's DRG hospital payment system, while not a fixed budget, provides more constraints than the previous cost-based reimbursement system.

CEA/CBA can be conducted from a variety of perspectives, including that of the individual, the family, the hospital, the insurer, or society. Many researchers agree that societal perspective is desirable for policy decisions. When private or program benefits or costs differ from social benefits and costs (and if a private or program perspective is appropriate for the analysis), the differences should be identified (353).

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[11] The main difference between CEA and CBA is the method of valuation of desirable consequences of a decision. In CBA, benefits (e.g., health outcomes) as well as costs are valued in monetary terms. In CEA, benefits are measured in nonmonetary units, such as years of life saved, days of morbidity avoided, or quality-adjusted life-years (which combine mortality and morbidity measures). The reason for a nonmonetary measure of benefits is either the impossibility or undesirability of valuing them in monetary terms.

The inherent conceptual and methodological strengths and weaknesses of CEA/CBA are addressed at length in previous OTA reports (353, 359) and later publications (347,420). A methodological issue of particular importance to the Medicare program in performing CEA/CBAs is whether to include discounted future medical care costs (due to longer life spans for patients resulting from the use of a medical technology) as a direct cost of the technology. Extending the life span of patients who are 65 years and older increases the chance that they will become high-cost consumers of medical care. Elderly people are particularly prone to chronic diseases.[12] And, about 80 percent of health care resources in the United States are used for chronic disease (321).

One can argue that future medical care expenditures should be included in an analysis of a technology's influence on medical care costs. Both public and private insurers are interested in how the use of a technology will affect their future expenditures. It is important to recognize, however, that reducing the measured benefits of a technology by the extra medical costs attributed to longer life biases the analysis against the technology. People consume medical care and other goods and services as long as they live. "To reduce benefits by a part or all of the value of this consumption may lead to the erroneous conclusion that prolongation of life is not worthwhile especially when consumption exceeds production" (417).

Another methodological issue that is of special interest to the Medicare program is whether the human capital approach should be used in valuing life in the analysis of a technology. The human capital approach values life in terms of earning potential; health outcomes are valued in terms of the economic productivity they permit (420). Because of its emphasis on economic productivity, the human capital approach values the lives of young people more than the lives of elderly people. The bias of the approach is most explicit in CBA. CEA, however, has built-in value judgments, i.e., once money is allocated to save lives, the value of life is implied. In CBA, the analyst must choose a value to complete the analysis; in CEA, the policymaker chooses the value, albeit indirectly (353).

It is important to bear in mind that CEA/CBA does not necessarily or easily take into account social values, moral judgments, legal implications or political realities. Thus, it does not easily or commonly address issues of equity and distribution.

The power of CEA/CBA is diluted in many instances not only by methodological problems but by a lack of efficacy data on which to base cost-effectiveness calculations. Some of the difficulties associated with these techniques will diminish with time, but others will not. An analysis rarely can account for the vast range of applications of a specific technology and the technology's unpredicted effects. The setting of care, volume of use, and the practice of medicine also influence the cost effectiveness of a technology.

Despite its limitations, CEA/CBA provides an analytical basis for integrating the economic aspects of a decision about medical technology with the health aspects. It can be very helpful in assisting the policymaker in structuring a problem and understanding its ramifications. As Fuchs says, "given the will and the mechanism . . . CEA/CBA offers the most rational human basis for effective, efficient allocation" (129).

Cost-Saving Technology

Definitional Complexities

The technical complexity of determining the cost effects of emerging and new technologies is compounded by the problem of defining a cost-saving or cost-raising technology. Differences in perspective impede arrival at a universal definition of a cost-saving or a cost-raising technology. The disparity in perspective may bring about conflict between parties because of the limited supply of resources for medical care.[13] If resources are used by one party, they are not available for use by another.

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[12] About 1 out of 10 40- to 50-year-old people has a chronic disease; by age 65, approximately 2 people out of 10 have a chronic disease; after 75 years of age, the number increases to 4 out of 10, and by age 90, almost 9 of every 10 people have a chronic disease (164).

[13] Costs of medical services are the economic resources (e.g., equipment, supplies, professional and nonprofessional labor, and the use of buildings) consumed in the provision of those services (423).

The question is: From whose perspective should the cost effects of a technology be examined? Are the cost implications of a technology to be considered from the perspective of the individuals, the hospital, the insurer, one Government program, the entire Government, society as a whole, or others? Each party has its own view of the cost effects of a particular technology, because health expenditures affect each differently. A technology that is considered cost saving by one may be considered cost raising by another. An associated question is: Is a cost-saving technology one that saves costs in the present or in the future?

For purposes of this study, a cost-saving technology might best be defined as a technology that saves Medicare program costs. Yet this definition does not distinguish between Medicare costs and societal costs—a distinction that may be required for policy decisions. Does the definition imply that the development, adoption and use of technologies that save Medicare program costs but raise societal costs should be encouraged or discouraged? One rationale for the Government's role in the health care system is "the promotion of the allocation of resources in the collective interest of the population of patients and potential patients" (423). Those who act on the belief that "Government agencies that plan and regulate the distribution of medical services may be viewed as agents for society" (423) would discourage technologies that decrease Medicare program costs but increase societal costs. Those who act on the belief that "Government agencies develop bureaucratic and organizational objectives that may not be consonant with the broader public interest" (423) would encourage technologies that decrease Medicare costs but increase societal costs.

Developing Criteria for Identifying Cost-Saving Technologies

Considering the difficulties in defining a cost-saving or cost-raising technology, it is not surprising that research on developing criteria to identify cost-saving technologies is in an early stage. One type of technology that can be identified as cost saving is a technology that substitutes exactly or very nearly for another and is also cheaper. The Shouldice method of hernia repair, for example, both substitutes for other methods of repairing hernia and is performed less expensively (166).

On the other hand, while it is generally accepted that the automated clinical chemical analyzer substitutes for previous nonautomated chemical tests, it is not clear whether the automated analyzer is producing more units of a formerly performed service or instead is producing a new type of laboratory analysis. Such distinctions, although often subtle and difficult to identify or measure, are crucial in analyzing the cost implications of technology.

Another problem in developing criteria is that the cost implications of a technology vary with the technology's stage of development: an assessment performed at one time may yield a different result when performed at another time. Technologies change over time. The dosages of a drug may be refined. New generations of devices replace old ones. Surgical procedures are modified. New, unanticipated uses, particularly for diagnostic technologies, are discovered.[14] Thus, the indications for using the technology change and its potential benefits and costs change over time.

Furthermore, the cost implications of a particular technology depend on the setting of care. For example, computerized energy management and bacterial susceptibility testing allegedly save hospital costs, but only if the size of the hospital and its volume are large enough to justify the investment (418). Thus, a technology that saves costs in one hospital may raise costs in another. Because of the variation among hospitals, reports about the cost-saving nature of one or another technology may be only partially accurate and have to be interpreted cautiously.

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[14] For example, the computed tomography (CT) scanner, a high capital investment instrument, was thought in the 1970's to increase the per unit cost of services (3). The current notion is that the CT scanner in fact may lower the per unit cost of health services by substituting for expensive, invasive procedures (420). If used appropriately, the CT scanner has the potential for decreasing health care costs, but it may increase health care costs when used inappropriately (347).

Attempts have been made to categorize technologies in hopes that distinctions can be made among types of technologies on the basis of expected costs and benefits (283). If all technologies within a category had similar pressures on cost and delivered similar benefits, a coverage policy could be designed using a categorical approach (283). Technologies with a common medical purpose (e.g., therapy) have some characteristics in common, and CEAs are conducted with them in mind. For example, the analysis of a treatment technology considers the effect of the technology on morbidity, disability, and/or mortality. But, it is difficult to identify the cost implications of such characteristics. There are, as well, characteristics not held in common among all technologies in a medical purpose category that may affect costs. **A method that is sufficiently sensitive to predict the cost implications of a particular technology based on its medical purpose category has not yet been developed.**

DISCUSSION

In the past, coverage policy has had important potential, but limited opportunity, to contain Medicare program costs by influencing the diffusion of medical technology. The Medicare provision that a technology must be covered before it can be paid for, however, may have protected beneficiaries from the indiscriminate adoption and use of technology and possibly from some unsafe and ineffective medical technologies.

The deliberate use of Medicare coverage to influence the adoption and use of medical technology, however, has been limited by several factors. These include Section 1801 of the Social Security Act, which prohibits Federal interference in the practice of medicine and the manner in which services are provided; the imprecise phrase "reasonable and necessary" governing the introduction of technology into the Medicare program; the decentralized mechanism for promulgating and implementing Medicare coverage policy; and the wide discretion allowed individual contractors in making coverage decisions.

Inadequacies in the current Medicare coverage process contribute to the circumscribed role of coverage policy in the rational diffusion of appropriate technology (26). The current coverage process does not ensure identification of all important new technologies that are introduced into the Medicare program or those covered technologies whose safety and efficacy has not been proved. Indeed, the universe of new technologies that are introduced into the Medicare program through contractors' coverage decisions is not known. The possibility that some new technologies are not identified but are paid for cannot be ignored. Medicare contractors vary in whether they cover (and then pay for) some particular technologies and in the extent to which they refer technologies to HCFA's central office for national coverage decisions. The absence of formal, legally binding requirements that contractors comply with national coverage decisions leads to the lack of uniform implementation of such decisions and a disparity in the coverage of technologies across the country.

Tightening the coverage process would no doubt save money for Medicare and would provide for a more rational diffusion of medical technology. It might also ensure equal access to the same technologies by Medicare beneficiaries. With respect to centralization, however, caution is necessary. A nationally controlled coverage process might not take into account the unique needs of all patients and could be administratively expensive. Thus, a decision to reduce variation in coverage policy and increase the explicitness and uniformity of Medicare benefits would require careful judgment and balance. Reconciling a more centralized coverage system with the independent practice of medicine could be a potential political problem.

The current process of evaluating medical technology at the national level may need modification in order to achieve the more rational diffusion of technology. Although the safety and effectiveness of technologies that are brought to the national level for coverage decisions are evaluated more rigorously there than at the contractor's level, the information available for an evaluation is often limited. The amount and type of data available vary for drugs, devices, and procedures. New drugs are subject to FDA's premarket approval requirements, and data on their safety and efficacy are usually available. For a drug to be considered for coverage, it must have FDA approval. (There is, however, no monitoring of drug use in hospitals.) Medical devices, depending on their classification, are subject to general controls, performance standards, or premarket approval requirements for safety and effectiveness by FDA.[15] However, few clinical trials have been performed on new medical devices submitted for coverage approval. Also, FDA's definition of effectiveness differs from that used for coverage. Analytic data on medical and surgical procedures, which are not subject to FDA regulatory requirements, are even less available than data on medical devices.

The guidelines used by OHTA to evaluate the safety, efficacy, and clinical effectiveness of medical technology stress the value of basing coverage judgments on information derived from controlled clinical trials or other well-designed clinical studies. Unfortunately, there is a dearth of such information—information from clinical trials of any type was available for only 2 of 12 full assessments published by OHTA in 1982 (352). Furthermore, even when such information is available, it often has limited value for coverage purposes. Very few clinical trials are designed to compare competing technologies. Most assess only one technology. Comparing the results of studies is often misleading because patient populations and study designs differ markedly. Few trials use individuals 65 years and older in the study population. Furthermore, few trials deal with questions about indications for use of a technology, and their results are not available soon enough to be included in a coverage decision. The lack of quantitative data is one force behind the statute (Public Law 98-21) that allows HCFA to fund controlled clinical trials of concern to the Medicare program.

Medicare may have further constrained the potential of coverage policy to influence the diffusion of technology by not limiting the coverage of certain technologies to specific providers and specific sites of care and by not explicitly considering costs in coverage decisions. In theory, one way to use coverage policy for containing program costs would be to include cost criteria in the assessment of medical technologies. But it appears that incorporating cost criteria into an assessment does not necessarily lead to the identification of cost-saving technology. Not only is a cost-effective technology not necessarily a cost-saving technology, but many experts contend that the definitional and methodological uncertainties of CEA/CBAs have not been sufficiently resolved for the use of these techniques as allocation tools. These techniques cannot provide decisions but can aid decisionmaking when used in conjunction with other kinds of information (353).

Finally, the relationship between coverage policy and DRG hospital payment needs further exploration. The importance of coverage policy will be only marginally diminished by DRG payment. Furthermore, the newly created ProPAC will assess DRG payment rates in association with the technologies that might be incorporated into those DRGs—an activity that represents the first explicit merging of costs and effectiveness in the Medicare program.

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[15] For more information, see OTA's forthcoming report *Federal Policies and the Medical Devices Industry* (345).

6.

Medicare Hospital Payment and Medical Technology

> Probably every new and eagerly expected garment ever put on since clothes came in, fell a trifle short of the wearer's expectation.
>
> *Charles Dickens*

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Medicare Hospital Payment and Medical Technology

INTRODUCTION

In 1982, over 70 percent of Medicare's payments was for hospital care (135). Furthermore, $34.6 billion (66.3 percent) of Medicare's $52.2 billion[1] expenditures was for *inpatient* hospital care (135,151), and between 1967 and 1982, Medicare program expenditures for inpatient hospital services increased at an annual rate of 19.2 percent (151,392). Given the importance of expenditures for hospital care in the Medicare budget, it is not surprising that both Congress and the executive branch have had a longstanding interest in controlling the growth of Medicare expenditures for hospital care.

Not only are hospitals important to Medicare, but the Medicare program and its methods of payment are crucial to hospitals. In 1982, Medicare accounted for 35 percent of hospitals' revenues (15). In 1980, as shown in table 17, Medicare and Medicaid together accounted for an estimated 42 percent of the revenues of a sample of short-term non-Federal hospitals. Because Medicaid hospital payment has traditionally followed the Medicare method in most States, the level and method of payment adopted by Medicare governs a sizable share of the total revenue of many U.S. hospitals. How Medicare chooses to pay hospitals—what it will pay for, how much it pays, and how it computes the level of payment—is therefore an issue of primary importance to hospitals, to the Medicare program, to communities, and to Medicare beneficiaries. Furthermore, hospitals are the major provider of medical technology, particularly sophisticated capital-intensive diagnostic and therapeutic procedures. Hospitals provide these technologies to both inpatients and outpatients. Changes in Medicare's hospital inpatient policy are therefore likely to affect the availability of medical technology for both kinds of patients.

Table 17.—Sources of Hospital Revenue,[a] 1980

Revenue source	Percent of total revenue
Medicare	34.1%
Medicaid	7.8
Blue Cross	16.1
Commercial	22.4
Other government sources	2.3
All other revenue[b]	17.3

[a] Based on a sample of 4,989 non-Federal, not-for-profit, short-term general hospitals.

[b] Includes operating, nonpatient care, and nonoperating revenues.

SOURCE: J. Feder, J. Hadley, and R. Mullner, "Poor People and Poor Hospitals: Implications for Public Policy," *J. Health Polit. Policy Law*, forthcoming.

As described in chapter 2, the Social Security Amendments of 1983 (Public Law 98-21) mandated a change in Medicare's inpatient hospital payment system from a retrospective, cost-based system to a prospective system of payment based on per-case prices for patients in 470 separate Diagnosis Related Groups (DRGs). DRGs are a set of patient classes developed to reflect differences in resource needs among different kinds of patients. Medicare's DRG hospital payment system is to be phased in over a 3-year period beginning in October 1983. The initial set of DRG prices is based on the 1981 average inpatient operating costs per case for each DRG in a 20-percent sample of Medicare claims. The prices will be updated regularly and will be adjusted for each hospital's urban or rural location and area wage rate. They will apply to virtually all short-term acute-care general hospitals in the United States. Under DRG payment, the hospital-specific maximum limit on the amount of inpatient operating costs per case that will be reimbursed will continue to be designated by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Public Law 97-248). Capital expenditures (depreciation and interest and return on equity for for-profit hospitals), direct teaching expenses, and expenses for outpatient services will remain "pass-through" items (i.e., items not subject to controls) as they were under TEFRA until the end of the transition period. Congress contemplated, but did not specify the method for, the incorporation of payment for capital into the DRG pricing system at the end of the 3-year period.

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[1] This $52.2 billion includes administrative expenses as well as benefit payments of $50.9 billion (135).

This chapter describes and analyzes how the incentives in Medicare's DRG prospective hospital payment system may affect medical technology adoption and use. Despite the recent establishment of the new hospital payment strategy for Medicare, it is quite possible that other approaches to hospital payment will be actively considered in the future. Part of the reason is that pressure for cost containment at the Federal level may continue, and part is that individual States may enact hospital cost control systems in which Medicare will agree to participate. Four alternative approaches to hospital payment that have been suggested or applied by public or private payers which might be considered for implementation by Medicare are considered in this chapter:

- alternative prospective payment programs and modifications of Medicare's current DRG system,
- capital payment methods,
- limited provider contracts, and
- increased beneficiary cost-sharing for hospital services.

The alternatives discussed in this chapter pertain only to payment of hospital care. They are not mutually exclusive, but are separated for ease of discussion.[2] Broader alternatives to the current Medicare payment methods, such as Medicare vouchers, which integrate payment for hospital services with that for other health care services, are discussed in chapter 8. Nevertheless, it is worth noting here that **strategies based on the continued independence of payment for hospital services from that of other health care services represent a limited field of opportunity for reform of Medicare payment.**

PROSPECTIVE PAYMENT OF HOSPITALS

Evolution of Prospective Payment Programs

The Medicare program is not the only third-party payer that has used retrospective, cost-based payment for hospital care over the years. In 1976 and 1981, for example, about one-half and one-third, respectively, of the Blue Cross plans reimbursed hospitals retrospectively on the basis of their costs (8,153). Furthermore, until 1981, State Medicaid programs were required to follow Medicare's principles of reimbursement for hospitals unless they applied for, and received, a waiver from the Federal Government for an alternative system.

In the late 1960's, however, some States and private third-party payers began the search for alternatives to retrospective, cost-based reimbursement, and alternative payment schemes, broadly termed "prospective payment," appeared in State and voluntary programs throughout the 1970's. Prospective payment programs vary widely, but they all have two features in common:

- the amount that a hospital is paid for services is set prior to the delivery of those services; and
- the hospital is at least partially at risk for losses, or is able to gain from surpluses that accrue during the payment period, or both.

The litmus test of whether a payment system is prospective is the extent to which a hospital's own decisions will alter the payment rate. Medicare's DRG payment system for hospitals is a particular type of prospective payment. The DRG system represents the culmination of years of experimentation with alternative forms of prospective payment by the States and private third-party payers.

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[2] For example, capital payment must be considered for all hospital payment alternatives.

The development by States of early prospective payment systems was spurred primarily by rising insurance premiums and Medicaid budgets. In several States, severe financial crises prompted their immediate implementation (155). Federal support of State-run prospective payment experiments was authorized by the Social Security Amendments of 1972 (Public Law 92-603), which gave added impetus to their development. Four States—Maryland, Massachusetts, New Jersey, and New York—have been granted waivers from Medicare's current payment system. These waivers give the State's rate-setting agencies the authority to set Medicare rates.

The oldest prospective payment program, sponsored by Blue Cross of Indiana, began in 1959 and remains in existence today. The first Blue Cross-sponsored prospective payment plans were voluntary programs in which participating hospitals' upcoming budgets were reviewed and approved by an appointed committee. The Blue Cross plan would then pay its share of the budgeted costs, rather than actual costs. Despite the fact that these systems were (or are) voluntary, hospitals were encouraged to participate because of the importance of Blue Cross as a source of revenues. The negotiated hospital budgets sometimes covered self-pay and commercially insured patients as well as patients in the Blue Cross plan. As might be expected given their voluntary nature and limited coverage, however, the Blue Cross-sponsored budget review programs have not been particularly successful in moderating cost increases (311).

State-mandated prospective payment programs have varied widely in their methods of payment and in the payers covered. The earliest State-run prospective program began in New York in 1970 and covered Medicaid and Blue Cross[3] (154). By 1979, there were 13 State-legislated prospective payment programs in effect throughout the United States (7), but the participation of hospitals was mandatory in only 10. These State programs evolved as their shortcomings were uncovered and as the crisis in hospital costs grew. Thus, current State-run prospective payment programs not only vary among themselves at present but also do not resemble their earlier forms.

In 1981, under the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35), State Medicaid programs were given expanded authority to deviate from Medicare reasonable cost reimbursement methods. As a result, several Medicaid programs have recently enacted prospective payment systems. Some of these Medicaid programs are part of statewide systems; other Medicaid programs have their own prospective payment systems.

Table 18 summarizes the status of mandatory State-level hospital prospective payment programs as of June 1983. At that time, 10 States had a State-legislated program, and another 17 States had a Medicaid-only hospital prospective payment program. Other States had State or local prospective payment programs in which participation and/or compliance was voluntary. One unique approach to hospital payment, discussed later in this chapter, is used in the Rochester, N.Y., area. Bills for the establishment of hospital rate-setting programs are currently under active consideration in six States: Florida, Pennsylvania, Ohio, Illinois, Indiana, and Wisconsin.

Key Features of Prospective Payment Systems

The details of program administration vary widely among prospective payment plans. Nevertheless, there are five components of prospective payment design that are likely to affect the incentives of hospitals to produce services and use technologies, and ultimately to influence the cost of hospital and health care. These are discussed below:

- **Payers covered**—The more payer classes covered by the prospective payment program, the more likely it is that the system will modify a hospital's decisions regarding the availability and use of services.
- **Unit of payment**—All prospective payment programs set hospital rates either explicitly or implicitly on the basis of one of five units of payment: 1) per service rates; 2) per diem

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[3] Medicare joined the program in 1980, and hospital charges made to self-pay patients and commercial insurance companies were frozen in 1978.

Table 18.—Mandatory State-Level Hospital Prospective Payment Programs as of June 1983

	Medicaid-only program	State-legislated program	Medicare participating in State-legislated program	Medicaid participating in State-legislated program
Alabama	X			
California	X			
Colorado	X			
Connecticut		X		
Florida	X			
Georgia	X			
Idaho	X			
Illinois	X			
Kentucky	X			
Maryland		X	X	X
Maine		X		
Massachusetts		X	X	X
Michigan	X			
Minnesota[a]		X		
Mississippi	X			
Missouri	X			
New Jersey		X	X	X
New York		X	X	X
North Carolina	X			
Pennsylvania	X			
Rhode Island		X		X
Utah	X			
Virginia	X			
Washington	X	X		
Wisconsin	X	X		
Total number of States	17	10	4	5

[a] Minnesota's system is mandatory in the sense that Blue Cross will not pay more than allowed rates.

SOURCE: U.S. Department of Health and Human Services, Health Care Financing Administration, unpublished data, May 1982; and R. Lyman, U.S. Department of Health and Human Services, Health Care Financing Administration, personal communication, June 20, 1983.

rates; 3) per case rates (per admission rates); 4) per case rates with adjustments for case mix;[4] and 5) per capita rates. Set prices for individual services give hospitals incentives to produce these services efficiently but also give them incentives to provide more services to each patient (389). A fixed payment for each day of stay establishes incentives to reduce the number of services offered per day but to increase lengths of stay as well. There is strong empirical evidence that these effects from a fixed rate of payment per diem actually occur (431). A fixed rate of payment per admission encourages low use of resources per stay and short lengths of stay but also establishes incentives for hospitals to increase admissions and to engage in "cream-skimming" to avoid more serious (and costly) patient types. Per case rates that vary by type of case, as in the Medicare DRG payment system, reduce but do not eliminate the incentive for cream-skimming but leave intact the incentive to increase admissions. Per capita rates, on the other hand, reduce the incentive to admit patients but encourage hospitals to agree to serve only healthier groups.

- **Scope of coverage**—Prospective payment programs vary according to the elements of hospitals' costs covered in the rates. The inclusion or exclusion of capital costs, teaching costs, and outpatient services in the prospective rate are important determinants of how the hospital and other providers behave, and ultimately how medical technologies are used. Hospitals have an incentive to shift services from cost categories with prospectively set limits to those that are still treated as "pass-through" items.
- **Extent to which a hospital's own costs determine the level of payment**—To be truly pro-

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[4] **Case mix**—The relative frequency of various types of patients, reflecting different needs for hospital resources. There are many ways of measuring case mix, some based on patients' diagnoses or the severity of their illnesses, some on the utilization of services, and some on the characteristics of the hospital or area in which it is located (343).

spective, a payment system should render a hospital unable to increase the level of payment by increasing its own costs. If the current payment rate depends on the hospital's past costs, with a 1- or 2-year lag, then the system is not very independent of the hospital's own cost experience, and the incentives in cost-based reimbursement will predominate. On the other hand, if the rate is set on the basis of the hospital's own costs in a base year with infrequent updating except for general inflation indexing, the relationship between cost and prospective price is effectively severed. Likewise, the use of comparative cost data from other hospitals to establish a hospital's payment limit also severs the link between the hospital's own past behavior and its prospective rate and will give the hospital more incentive to contain costs.

- **Program stringency**—Under any particular payment method, a program can be either generous or restrictive. A stringent program is one in which the payment level is low relative to the cost of providing services. Program stringency is a function of numerous aspects of a program's design. For example, a program may or may not allow hospitals to keep any surpluses generated as a result of cost-saving behavior, or it may penalize hospitals more or less severely when costs run above the prospective level. Although overall program stringency is difficult to measure precisely, a rough indicator is the ratio of net revenues to total expenses from those patients covered under the prospective payment program. If the ratio is high, then the program is relatively generous; if it is low, then the program is stringent. Under a stringent method, the hospital must cover operating losses with cash from gifts, depreciation allowances, or revenues from other sources.

Some have argued that program stringency is the most important factor in the effectiveness of prospective payment programs in reducing hospital costs (64). The stringency of the program is likely to affect the ability of the hospital to generate capital from both internal and external sources. Hospitals operating under more stringent programs therefore would be likely to face higher capital costs, which in turn would affect the adoption of capital-intensive medical technologies.

Effects of Prospective Payment on Medical Technology

There is evidence to suggest that in recent years, some State-level mandatory prospective payment programs have had a moderating influence on hospitals' costs (36,64,309,310). A recent study of 15 State or areawide hospital rate-setting programs found that the rate of increase in total expenses per hospital admission was reduced by approximately 2 to 5 percent between 1969 and 1978 in seven States with mandatory programs (64). Apparently, prospective payment programs need time to mature before they begin to influence hospital costs (310). Using national data for the period 1969-80, Sloan estimated that mandatory State prospective payment systems ultimately reduce hospital expenses per adjusted admission by an average of 13 percent relative to States without such systems (309).

That prospective payment can reduce hospital expenditures does not necessarily imply that the use of medical technologies will decrease. In fact, one would expect prospective payment to have different kinds of effects on different technologies (see ch. 3). One indirect method of examining hospitals' technology choices under prospective payment is to study the effect of prospective payment on a related measure: hospitals' choices of labor and nonlabor inputs to the production of services. **If prospective payment makes hospitals more efficient producers of services, both a reduction in the total value of inputs and substitution among different kinds of inputs should be observed.**

Studies of the impact of prospective payment on hospitals' use of labor have documented both a decrease in the total number of hospital employees and a substitution of less expensive for more expensive personnel in States with strong rate-setting systems (132,179,187). There is no evidence on whether hospitals reduce nonlabor inputs under prospective payment systems or whether such systems lead to substitution between capital- or material-intensive inputs and personnel.

There is some evidence regarding the effect of prospective payment on the provision of medical services. As part of a comprehensive study of nine State-legislated hospital rate-setting systems, Worthington and Piro (431) found that programs that pay hospitals on the basis of a per diem rate all produced an increase in the average length of stay and the occupancy rate. This result would be expected from a per diem rate-setting system, because the longer the patients stay, the more revenue the hospitals receive. Although a per diem rate-setting program would also be expected to encourage increases in inpatient admission rates, no such admission effects were found in this study. These results suggest that manipulating hospital admission rates may be more difficult than increasing the length of hospital stay for patients already admitted. **Taken as a whole, however, the results do suggest that decisionmakers in hospitals respond in predictable ways to financial incentives for the use of hospital services.**

A related question with important long-run implications for medical technology is whether prospective payment influences the extent and speed of hospitals' adoption of new technologies. Studies of the impact of hospital prospective payment programs on the adoption of new capital equipment or "technology-intensive" services suggest that prospective payment can have an effect on technology adoption and that the nature of the effect depends on both the specific attributes of the program and the characteristics of the new technology.

Joskow (182), who analyzed the effect of rate-setting programs on the availability of computed tomography (CT) scanning in hospitals, found the number of CT scanners in a State in 1980 to be negatively related to the number of years that rate-setting had been in effect in the State.[5] Hospital rate-setting also led to a shift in the location of CT scanners to physicians' offices.

Cromwell and Kanak (77) recently analyzed the impact of 15 State rate-setting programs on the availability of 13 different services in the hospital between 1969 and 1978. New York's rate-setting program, a restrictive program that pays per diem rates, had the most consistently negative effects on the availability of all types of services. New Jersey's pre-DRG prospective payment system also appeared generally to reduce the availability of complex services. Other States' programs showed no consistent impact on service adoption. It is interesting to note that the service upon which rate-setting had the largest and most widespread negative effect is social work, a labor-intensive, not equipment-intensive, hospital service.

In still another study of hospital payment and technology diffusion, Wagner, et al. (418), investigated the impact of prospective payment in three States (New York, Maryland, and Indiana) on the adoption of five new pieces of capital equipment: electronic fetal monitoring, gastroendoscopy, volumetric infusion pumps, automated bacterial susceptibility testing, and computerized energy management systems. The first three technologies probably raise the daily cost of care, although their effect on the average cost per case is unknown. The latter two are investments in cost-saving equipment. The New York rate-setting system was found consistently to lead to adoption of fewer units of cost-raising technologies and to increase the probability of large hospitals' adopting cost-saving equipment. However, the prospective payment programs in Maryland and Indiana showed no such consistent effects on hospitals' adoption behavior.

Together these studies imply that prospective payment does affect the adoption of new technology in predictable ways but that much depends on the strength and design of the program. New York's system, the oldest and most restrictive rate-setting program, has clearly altered the extent of availability of new technology. Other systems may be too new, too small, or too generous to show long-run consequences.

Medicare's DRG Payment System and Medical Technology

Features of Medicare's DRG prospective hospital payment system currently being implemented create strong incentives for hospitals and other providers to use and adopt technologies in ways that are different from those under cost-based reimbursement. Although the DRG hospital payment system does not include payers other than Medicare, the per case payment approach provides incentives to hospitals both to reduce the amount of resources expended per stay and to selectively encourage admissions.[6] These incentives are strengthened because the payments hospitals receive for treating patients are essentially unaffected by the hospital's own costs and because the system puts hospitals entirely at risk for losses.

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[5] The analysis controlled for possible impacts of other types of hospital regulation, including certificate-of-need (CON) laws.

During the 3-year period of the DRG system's implementation, several key elements of hospital expenses, including capital, teaching, and outpatient expenses, will continue to be paid as pass-throughs. Inputs that are passed-through become less expensive to the hospital relative to inputs subject to controls and theoretically should be used more by hospitals. To discourage hospitals from increasing capital expenditures in anticipation of future controls, the Social Security Amendments of 1983 (Public Law 98-21) deliberately left uncertain whether capital expenditures for new projects begun in the first 3 years of the law's implementation would or would not be included in prospective per case limits at the end of the 3-year period.

Although there is no empirical evidence on the effect of the new DRG inpatient hospital payment system, it is possible to describe how the incentives inherent in the system may alter the use of medical technologies. First, however, it must be stressed that financial incentives are but one of several influences on hospitals' decisions to adopt and use technologies. **DRG payment will not have a uniform effect on medical technologies, and in some instances, technologies will be subject to conflicting incentives.** In general, the following can be concluded:[7]

- Under DRG payment, the number and intensity of ancillary procedures provided to inpatients can be expected to decrease overall, but the use of ancillary procedures that can be shown to lower the cost per case can be expected to increase.
- The settings of technology use are likely to be influenced by DRG payment, but the incentives work in conflicting directions and are sensitive to the key features of program design. For example, in the absence of a method for excluding very low-cost patients from the DRG pricing system, DRG payment encourages inpatient admissions for simple procedures. It remains to be seen which incentive will dominate for which procedures. DRG payment will encourage the movement of technologies, particularly those for post-hospital care, into the home and other nonhospital sites of care.
- DRG payment is likely to influence the specialization of services, but the magnitude and direction of these effects is unknown. The incentives to reduce costs encourage concentration of capital-intensive technologies in fewer institutions. Conversely, increasing competition among hospitals for physicians and patients may create incentives for the widespread acquisition of some technologies.
- A change in technology product mix is likely to result from downward pressure on the price and quantity of supplies and, if capital

Photo credit: E. I. du Pont de Nemours & Co.

DRG payment will affect the settings of medical technology use. Some services provided formerly in the hospital will be provided in increasing numbers on an outpatient basis

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[6] The incentive to selectively increase admissions is somewhat moderated by the fact that the hospitals receive different payments for different types of cases. It is not entirely abolished, however, because of the imperfections in the use of DRGs as the case-mix measure.

[7] These conclusions are based on a detailed analysis of DRG payment conducted as part of this project and published in a technical memorandum entitled *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343).

> is included in the DRG rate, capital equipment. Greater product standardization can be expected as more expensive models and procedures are eased out of the market through competition.

It is also possible to describe the incentives regarding the adoption of new technologies and the discarding of old technologies under DRG payment. Many observers have pointed out that per case payment systems in which future levels of payment are largely independent of the hospital's own historical costs create incentives for hospitals to adopt cost-saving technologies—i.e., technologies whose adoption decreases the *hospital's* total cost per case. Given that technologies are neither cost saving nor cost raising independent of the context in which they are used, however, the same technologies are not likely to be adopted by all hospitals. The introduction of new capital-intensive cost-saving technologies in a DRG payment environment is likely to encourage specialization among hospitals as small hospitals become unable to reap the cost-saving benefits of some investments. Some technologies that depend on high volume to be cost saving might be provided to smaller hospitals on a contract basis by large hospitals or independent laboratories. The feasibility of such contractual arrangements would vary depending on the specific uses of technology and the geographical and competitive environment in which the hospitals operate.

The financial incentive to introduce new cost-raising technologies (i.e., technologies whose adoption increases the *hospitals'* total cost per case) is lessened, but not eliminated, under DRG payment compared to cost-based payment. Under cost-based payment, the additional hospital costs of new technologies are covered; hospitals therefore have no financial incentives not to adopt such technologies. Under DRG payment, a hospital's adoption of new cost-raising technology is not met with an automatic increase in revenues to cover the additional cost. New technology will have to compete with alternative uses of hospital funds, such as employee wage and benefit increases or additional nursing staff. New technology may be at an additional disadvantage relative to other uses of funds because of the relative uncertainty about its benefits in the early stages of diffusion (282). The implications are obvious: with limited resources, hospitals will need to assess new technologies more closely and ration resources more carefully.

Nevertheless, the introduction of promising new technologies, even those that are cost raising to the hospital, will be attractive to hospitals as they compete for physician loyalties and, ultimately, the admissions they represent. For example, despite its high capital and operating cost, nuclear magnetic resonance imaging, a new medical imaging technology still in the investigational phase, may be highly desirable to hospitals who seek to protect their admissions base from encroachment by other hospitals. The importance of this incentive as a constraint on the incentive not to adopt new technologies is unknown. Thus, **although DRG payment does not imply that technological change will approach a standstill, the directions of such change are likely to be altered. Overall, the adoption of technologies that are cost raising to the hospital is likely to decline by an unknown quantity.**

Per Capita Prospective Payment

Per capita prospective payment to hospitals refers to an array of methods for paying rates to hospitals in advance based on the number of enrolled or covered individuals rather than on the services provided, days of care, or admissions. A single organization consisting of one or more hospitals takes responsibility for providing all covered hospital benefits to the beneficiary during a specific period of time in exchange for a fixed rate of payment. Beneficiaries may or may not be limited in their choice of place of hospitalization. Under free choice plans, the hospital receiving the per capita payment would have its payment reduced by the payments made to other hospitals for services to the beneficiary. Presumably, the hospital receiving the per capita payment has a financial incentive to see to it that the amount and intensity and, therefore, the cost of hospital care is reduced.

Per capita hospital payment is one of the oldest types of hospital payment mechanisms (303). This approach emerged from individual hospitals' efforts in the 1920's to stabilize their revenue sources. As the notion of beneficiary free choice gained prominence with nonprofit health insurance plans, however, payment of hospitals on a unit-of-service basis became the norm. Thus, for almost 20 years—from 1946, when the last individual hospital per capita payment plan closed down, until 1964 when the Colorado Blue Cross plan initiated such a program in one county—per capita payment of hospitals was nonexistent in the United States (303). The Colorado Blue Cross program lasted 18 months but was abolished with the emergence of Medicare and Medicaid (303).

In 1980, the Blue Cross and Blue Shield Association, with funding from the John A. Hartford Foundation, initiated two demonstrations of per capita hospital payment involving beneficiary free choice (90). In 1982, 10 hospitals in 2 States (North Dakota and Massachusetts) began receiving per capita payments in an effort to demonstrate that per capita payment would lead to more efficient provision of hospital care (90). Individual hospitals in these demonstrations have no control over the beneficiaries "assigned" to them. The assignments are made either by the beneficiaries themselves or by the Blue Cross plan. Per capita rates vary with beneficiary characteristics and are based on the hospitalization experience of each group. Thus, an attempt is being made to avoid the problems of cream-skimming—the tendency of hospitals to avoid serving sicker populations—and adverse selection—the tendency of high-risk beneficiaries to seek out more comprehensive and costly care.

Unlike per case prospective payment, per capita hospital payment is designed to encourage hospitals to reduce the rate of admission to hospitals and to expand the use of pre- and post-hospital care outside of the inpatient setting. Since beneficiaries in the demonstrations maintain the right to choose freely their hospitalization site, the success of the program appears to hinge on the degree of cooperation between hospitals and physicians in managing the hospital resources efficiently.

Data are not yet available on the effect of the demonstrations on the use of hospital and other health care services or on hospital costs. However, two observations can be made about the applicability of such an approach to Medicare. First, implementation of per capita payment (especially with free choice of provider) depends on the availability of excellent patient-based data systems through which estimates of per capita costs can be made. Second, the process of "assigning" beneficiaries to "home" hospitals may be feasible in certain communities but may not be universally feasible. Especially when beneficiaries maintain the freedom to choose their place of care, per capita hospital payment may depend for success on the existence of specific hospital market environments.

As with any prospective payment system that encourages hospitals to become more economical in the provision of services, per capita payment runs the risk of discouraging hospitals from providing needed care. In this case, the risk is to underadmit as well as to underprovide services while in the hospital. Finally, per capita payment would be likely to affect the adoption of medical technologies in ways that are similar, but not identical, to the expected effects of DRG payment. For example, whereas DRG payment encourages hospitals to adopt new technologies which will bring in new admissions, per capita payment has the opposite effect.

Areawide Global Prospective Budgeting: The Rochester Area Hospitals' Corp.

Nine hospitals in the Rochester, N.Y., area have been experimenting since 1980 with a global prospective budgeting approach to hospital payment (40,280). The nine member hospitals of the Rochester Area Hospitals' Corp. (RAHC), accept a cap on the aggregate revenues they can receive each year. The areawide revenue cap is developed from the member hospitals' actual costs in a base year (1978) with adjustments for inflation and technological change in subsequent years. Individual hospitals' budgets are allocated from the total in a similar fashion, but some of the revenues are withheld in a special fund to adjust for the cost of increases in admissions and for new equipment or facilities approved by both RAHC and the State. The RAHC board has the responsibility for distributing these special funds among hospitals

(319). The hospitals are collectively responsible for keeping expenses within the global budget; if areawide admissions increase to the point that the special fund is exceeded, the hospitals must share in absorbing the excess costs.

The experimental global budgeting program in Rochester clearly involves negotiation among hospitals in dividing up available funds for service expansion and modernization. Whether the concept can survive in the long run remains to be seen. In any case, Rochester has some special attributes that make it a particularly fertile environment for such an experiment. First, the hospitals' market area is relatively self-contained and well defined. A global budgeting approach would not be feasible where market areas are not easily defined. Second, the Rochester area has a long history of business, community, and hospital support for areawide planning (319). An earlier experiment funded by the Federal Government, which included a larger area of New York State as well as Rochester, collapsed (319), probably because these two factors were not present.

If successful, Rochester's global budgeting approach would represent an application of allocation of health care resources through a political process. There is clearly an incentive for each hospital to increase its admissions at the expense of others, but without access to funds for new services, the member hospitals may be effectively constrained from doing so. It is not clear how rationing resources on a community level would affect specialization of services or regionalization of facilities. Evidence on the effects of the Rochester experiment is not available at this time. The potential for such an approach as a method for rationing hospital technologies may be great in a few areas of the country where social, political, and demographic conditions are right, but for the reasons given above, it is not likely to be viable as a general approach to hospital payment.

CAPITAL PAYMENT METHODS

The use of new medical technology often depends on hospitals' making investments in capital facilities and equipment. Hospitals' willingness and ability to make these investments in "equipment-embodied technology" (233) are influenced by the third-party hospital payment system. Consequently, an important issue with respect to the diffusion of medical technology is how Medicare pays for hospital capital.

It is important to recognize that **the effects of any capital payment method depend on the larger payment system of which the capital payment method is a part**. Thus, for example, a particular approach to capital payment would have different effects on the use of medical technologies under a cost-based reimbursement system than under a prospective payment system. The history of payment for capital under Medicare's traditional cost-based hospital reimbursement system and under State prospective payment systems is described below. Also discussed below are capital payment options under Medicare's DRG prospective payment system, which is currently being implemented. The capital payment method under DRG prospective payment was left unresolved in the Social Security Amendments of 1983 (Public Law 98-21), so detailed examination of the implications for medical technology of various capital payment approaches under DRG payment is both important and timely.

History of Capital Payment Under Medicare

Medicare's cost-based hospital reimbursement system has had strong effects on hospitals' capital acquisition decisions. Traditionally, Medicare has reimbursed hospitals for interest and historical cost depreciation expenses associated with all capital equipment purchases, regardless of whether the equipment was purchased or leased. In theory, when combined with cost-based reimbursement of operating costs, this approach to capital payment encourages hospitals to invest in new facilities and equipment and to finance as much as possible through debt. If a hospital persistently "funds" payments for depreciation (i.e., establishes a separate fund that cannot be used for operating expenses), cost-based reimbursement provides the cash necessary to amortize whatever level of debt the hospital incurs. If all hospital revenues were derived from cost-based payers, capital, as well as all other inputs, could be used in unlimited quantities.

The situation was more complicated in practice. Some experts have claimed that Medicare's cost-based payment system did not pay its fair share of hospital costs, because it did not pay for a share of bad debts and charity care attributable to patients other than Medicare beneficiaries (71). Consequently, hospitals with high burdens of unpaid care and large numbers of Medicare and Medicaid beneficiaries have incurred deficits. Such deficits could only be accommodated by the cash flow generated through depreciation payments or other sources of cash such as unrestricted gifts or non-patient-care revenues. Hospitals with a high proportion of patients covered by insurance plans paying on the basis of charges have had an advantage over others, because they could recover the costs not covered by Medicare for these patients by raising their charges. Other factors being equal, hospitals with a high proportion of patients subject to cost-based reimbursement are likely to receive lower bond ratings[8] than other hospitals (70). Thus, while cost-based reimbursement under Medicare increased hospitals' demand for capital, over time it has also made it more difficult and costly for some hospitals to obtain additional debt financing.

Capital Payment Under State Prospective Payment Programs

With exceptions noted below, those responsible for designing State prospective payment programs have been reluctant to deviate from cost-based reimbursement for capital. Even New York's otherwise restrictive rate-setting program, for example, continues to treat capital expenses as pass-throughs, much as in the Medicare system (154). Payment for capital in some States has been even more generous than under Medicare. Washington, Massachusetts, and Minnesota have used price level depreciation rather than historical cost depreciation (76). Maryland and New Jersey calculate a capital facilities allowance for buildings and fixed equipment that provides cash sufficient to pay off existing debt and to accumulate a down payment for replacement or additions. In all of these cases, the hospital's payment rate depends on its own capital expenditures.

States have generally looked to the direct regulation of capital expenditures through certificate-of-need (CON) laws as a capital rationing device. CON laws require that hospitals receive approval from a State health planning agency for major capital investments. Although there is a general consensus that capital expenditure regulation as implemented in the States has not been effective in reducing the level of capital expenditures (69,414), most rate-setting programs assume that the appropriateness of capital investments will be judged through CON.

The only deviations from cost-based reimbursement of capital have been Maryland's and New Jersey's approach to payment for major movable equipment (e.g., beds, diagnostic instruments) and western Pennsylvania's approach to capital payment. In Maryland, the depreciation on major movable equipment available in the hospital in a base year is adjusted in subsequent years by an appropriate inflation factor. The allowance for movable equipment is unaffected by the hospital's subsequent capital expenditure decisions, except for special cases in which the rate-setting commission may make exceptions (185). New Jersey's DRG system has a similar method for major movable equipment. The allowance is adjusted for inflation from a base year, which is updated periodically. Unlike Maryland's allowance, however, the rate of reimbursement for major movable equipment is a blend of the hospital's own capital costs and those of other peer group hospitals (416). In the western Pennsylvania program, hospitals have a choice of historical cost depreciation not exceeding 4 percent of other allowable costs or any other method that results in less than 3 percent of costs (76). Thus, hospitals in western Pennsylvania are subject to an effective ceiling on capital reimbursement.

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[8] Bond rating is an assessment of the credit worthiness of a hospital by a rating agency such as Standard & Poor's Corp. or Moody's Investors Service.

Capital Payment Alternatives Under DRG Payment

What method of payment for capital will eventually be adopted under Medicare's DRG hospital payment system remains to be seen. The Department of Health and Human Services is required by law to report to Congress by October 20, 1984, on a recommended approach to capital payment. For the time being, capital expenditures by hospital will continue to be reimbursed as before—on a cost basis.

Figure 3 presents the major alternatives for capital payment under Medicare's newly created DRG hospital payment system. **The fundamental issue under DRG payment is whether a hospital's capital payment should or should not be subject to some kind of externally imposed limit.**

Pass-through reimbursement of capital could continue as a permanent feature of DRG payment. As shown in figure 3, there are three alternative pass-through approaches:

- payment of historical cost depreciation and interest expenses,
- payment by price level depreciation, and
- payment of debt service requirements.

In all of them, the level of payment is directly linked to the amount of capital investment undertaken by the hospital.

Payment of historical cost depreciation and interest expenses represents a continuation of the traditional Medicare method. Payment by price-level depreciation, with hospitals paid according to the current value of the capital assets used up in any year, would be more generous than historical cost depreciation in an inflationary economy. Finally, payment by Medicare of its share of the hospital's debt service requirements would match the flow of capital payments over time more closely with the actual flow of debt payments. In any of these cases, the hospital would receive cash sufficient to cover its debt over the lifetime of an asset.[9]

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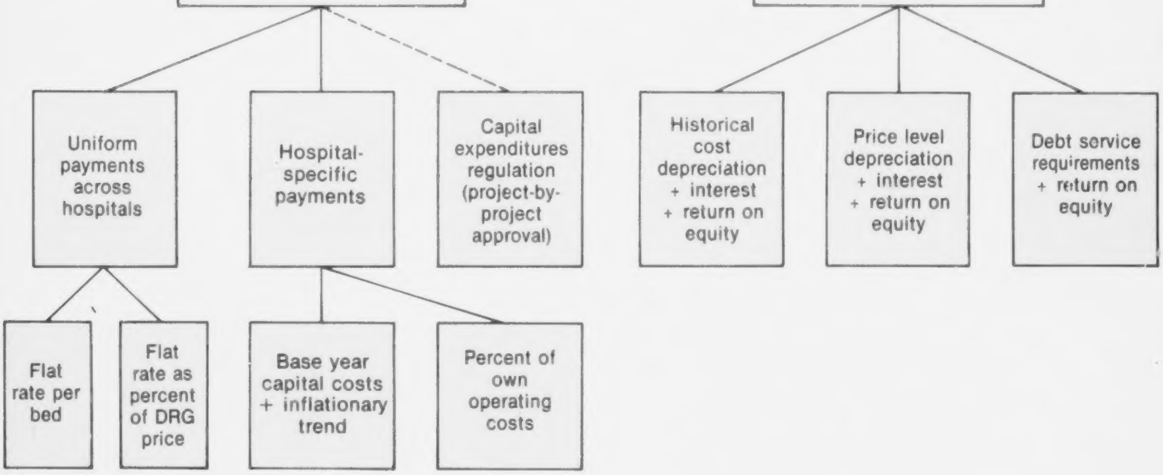
[9] Investments using equity capital rather than debt instruments could be paid depreciation and a return on equity. The issue of which hospitals should receive a return on equity capital and how high this return should be is clearly important to the hospital industry, but it is not a central issue with respect to medical technology and is therefore not discussed in this chapter.

Figure 3.—Options for Capital Payment Under Medicare's DRG Hospital Payment System


Controlled payments
Pass-through payment
Uniform payments across hospitals
Hospital-specific payments
Capital expenditures regulation (project-by-project approval)
Historical cost depreciation + interest + return on equity
Price level depreciation + interest + return on equity
Debt service requirements + return on equity
Flat rate per bed
Flat rate as percent of DRG price
Base year capital costs + inflationary trend
Percent of own operating costs

SOURCE: Office of Technology Assessment

Methods of limiting capital payment fall into three categories:

- methods that establish uniform rates of payment across all hospitals (or all within a class),
- methods that establish hospital-specific controlled rates, and
- methods that condition payment on approval of capital expenditure projects.

The uniform payment approach would treat all hospitals alike, regardless of their capital or operating expenditures. The uniform payment could be calculated either as a fixed percentage of the DRG price or as a flat rate per bed. Hospital-specific approaches, on the other hand, would take the hospital's capital or operating costs into account in establishing a level of payment but would limit increases in the payment level over time. Thus, for example, capital payments could be limited to a percent of operating costs, so that hospitals with high operating costs would receive a higher capital payment than others; alternatively, the capital payment in any year could be tied to the hospital's actual capital costs (as measured by interest and depreciation) in a base year with adjustments for inflation in subsequent years. If capital payments were controlled through direct regulation of capital expenditures, only projects approved by a CON or other designated agency would be recognized by Medicare for capital payment. Approved projects would then be paid on a cost basis. Areawide or statewide annual capital expenditure limits could be used to establish an upper bound on the value of approved projects. The State of New York is currently considering adoption of such a capital expenditure limit.

The alternative capital payment methods described above can be evaluated on the basis of four general criteria:

- **Efficiency**—The extent to which the approach promotes the cost-effective use of hospital technology. An ideal method would not distort the relative costs to the hospital of capital and other inputs, would discourage needless duplication of capital-intensive services in the community, would encourage specialization and regionalization of services when appropriate, and would minimize the cost of providing any given level of hospital care.
- **Equity of access to medical technology**—The extent to which the method promotes equal access to capital-embodied medical technology. An ideal method would not deny people living in certain regions or with low incomes access to medical technology that is available to others.
- **Fairness**—The extent to which the method treats all kinds of hospitals alike. An ideal system in this respect would not reward or penalize hospitals according to their ownership status, location, or other factors that lie outside management's control.
- **Feasibility**—The extent to which the method is administratively workable and politically acceptable. An ideal method would involve low administrative costs, minimize the problems of transition from the old to the new payment method, and accommodate the inherent cyclic nature of hospital investments.

A permanent capital cost pass-through under DRG payment violates the efficiency criterion, because it distorts incentives for hospitals to adopt and use capital-embodied technologies. Table 19 shows how a pass-through for capital expenditures influences hospitals' incentives to adopt four different kinds of hospital technology under DRG per case payment. So long as the effect of medical technology acquisition on a hospital's total cost per case is in the same direction as its effect on operating costs, for example, the method of capital payment under DRG payment will not alter the direction of the incentives for technology adoption. Thus, there are disincetives under DRG payment to adopt most quality enhancing, cost-raising (Type I) technologies regardless of the way in which capital is handled. Capital cost pass-throughs weaken the disincentive to adopt such technologies, but they do not remove it. New technologies with high capital costs but only small increases in operating costs would be affected less by DRG payment with a capital pass-through than by DRG payment with capital built into the rate.

Of course, since DRG payment sets up incentives for hospitals to increase admissions, hospitals

Table 19.—Impact of Technological Innovation on Per Case Costs Under DRG Payment

	Direction of effect on costs:			Incentives for technology adoption	
Type of innovation	Capital cost per case	Operating cost per case	Total cost per case	With capital in rate	Without capital in rate
I. Cost-raising, quality-enhancing new technology	+	+	+	↓	↓
II. Operating cost-saving innovations					
A. Raises total costs	+	–	+	↓	↑
B. Saves total costs	+	–	–	↑	↑
III. Capital cost-saving innovations					
A. Raises total costs	–	+	+	↓	↓
B. Saves total costs	–	+	–	↑	↓
IV. Service/procedure disadoption	–	–	–	↑	↑

SOURCE: Office of Technology Assessment.

can be expected to seek cost-raising technologies whose availability promises to bring in profitable admissions. A capital cost pass-through essentially subsidizes this kind of investment, leading potentially to wasteful duplication of these services among hospitals.

In the case of operating-cost-saving (Type II) and capital-cost-saving (Type III) technologies, the incentives for hospitals to adopt may actually be reversed by the policy regarding payment for capital. Of particular concern is the incentive under a pass-through to adopt expensive capital equipment that reduces operating costs but raises total cost per case. Automated hospital information systems, for example, could be evaluated in terms of their ability to reduce operating costs with inadequate regard for their impact on total costs. The more labor-saving capital-intensive system would be preferred regardless of its net impact on costs. Over time, then, hospitals could be expected to become more capital intensive than efficiency would dictate.

Despite the inefficiency inherent in a capital cost pass-through, this approach does well on the other three criteria. Its feasibility has been demonstrated through the years. It is inherently fair because all hospitals are treated alike in their payment. Finally, it poses no barriers to equal access to medical technology, although it does nothing to redress current inequities. Public and inner-city hospitals tend to have lower ratios of capital to total costs than other hospitals, because these hospitals have older facilities and possibly less equipment-embodied technology (20,188,356).[10] A cost-based system of reimbursement for capital would continue to pay these hospitals relatively less than other hospitals. Because public and inner-city hospitals typically have a high burden of bad debts and indigent care, their reimbursement from depreciation costs is often used to assist their cash flow to subsidize the operating costs associated with this uncompensated care. Since it is unlikely that the implementation of DRG payment will do much to change the situation, hospitals with low levels of capital assets will continue to receive low payment under a capital cost pass-through.

Despite the low level of capital payment, some hospitals serving poor areas may find their ability to raise capital enhanced by DRG payment with a capital cost pass-through. These hospitals now have the potential to generate operating savings which could be used to offset operating cost losses on bad debts and charity care.

Controlled capital payment is generally more efficient than pass-through capital payment, because the hospital is encouraged to provide its care at the least possible cost. New technologies would be judged by hospitals in terms of their impact on total costs, not just on operating costs. Hospitals would be further encouraged to specialize and join in plans for regionalization of health services. However, it is difficult to devise a controlled payment system that is fair to all hospitals. In a uniform payment system, hospitals that in the past have had lower ratios of capital to operating cost would receive more than they had in the past, while those with high ratios would receive less. Thus, public hospitals would, at least in the near term, fare better under a uniform system than they had in the past. But uniform payment of capital also favors multihospital systems, because it allows these affiliated hospitals to pool capital payments and smooth out fluctuations in capital expenditures across hospitals.[11] A uniform rate of payment would also create a difficult and possibly costly transition if hospitals that have made major investments in recent years are not to be unduly penalized. The American Hospital Association has recently proposed a uniform capital payment system that would pay each hospital the higher of cost-based reimbursement or a fixed payment rate during a 10-year phase-in period (9). Andersen and Ginsberg have suggested a less generous transition in which "budget neutrality"[12] is maintained by gradually reducing the proportion of the capital payment that is a pass-through (15).

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[10] For example, the mean percentage of capital costs to total costs for non-Federal public hospitals in 1981 was 5.2 compared to 6.7 for private not-for-profit hospitals and 8.9 in for-profit hospitals (15).

Tying the capital payment to the level of capital costs in a base year or to the hospital's operating costs is efficient but may be unfair. This approach tends to reward the hospitals that were most capital intensive in the past, leaving those with low levels of capitalization forever to receive lower payments. Moreover, this approach would not work well for hospitals requiring major capital expenditures in the early years of implementation. Perhaps for these reasons, support for this approach has been limited to the movable equipment portion, which typically has shorter lifetimes and lower variations in asset values among hospitals.

It is difficult to predict the effects of direct regulation of capital expenditures through CON or other agencies. Direct regulation can occur with or without statewide or areawide maximum limits on the total capital outlays over a given period, and the effects can be expected to differ between the two. Although there has been much discussion in certain States about establishing capital expenditure limits or "pooling" capital, all experience to date has been with CON and Section 1122 programs which do not operate with areawide or statewide limits. The experience with capital expenditures regulation in the absence of such limits has been disappointing, with most evaluations concluding that the level of capital expenditures has not been affected (65,69,251,414). Moreover, the distribution of medical technologies among hospitals does not appear to have been improved as a result of CON (65).

The institution of an annual (or perhaps, long-term) limit on the level of capital expenditures that can be approved by CON agencies would, if it were strictly enforced, ensure that the program has an effect on the total level of capital expenditures. But there is no evidence, either theoretical or empirical, to suggest that the outcome of such a regulatory process would be either efficient or fair (417). A review of the literature on resource allocation decisions by committees revealed that the ultimate outcomes depend both on chance and on the composition of the committee and the procedures governing the decisionmaking process (417). Moreover, the kinds of information needed to make informed tradeoffs among competing capital projects is likely to be unavailable, thus leaving the process even more exposed to political solutions.

Regardless of whether or not an areawide limit is applied, direct regulation of capital expenditures is administratively feasible only for large projects—construction and renovation projects and major new services. The current trend toward high thresholds for inclusion in capital expenditure controls (256) would probably continue, leaving an ever larger proportion of capital-embodied technology needing to be controlled in some other way.

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[11] At present, approximately 26 percent of all community hospitals are members of multihospital systems. About 11 percent of these systems are proprietary; the remainder are government or not-for-profit systems (51).

[12] "Budget neutrality" means (as specified in the Social Security Amendments of 1983) that the aggregate payments for the operating costs of inpatient hospital services in fiscal years 1984 and 1985 will be neither more nor less than would have been paid under the Tax Equity and Fiscal Responsibility Act of 1982 for the costs of the same services.

LIMITED PROVIDER CONTRACTING

Another approach to hospital payment has arisen following recent legislation. In 1981, under Section 2175 of the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35), Congress gave States greater flexibility in restricting Medicaid beneficiaries' freedom to choose their providers of medical care. Under this statute, State Medicaid agencies are permitted to apply for waivers from the freedom-of-choice provision of the Social Security Act. Most waivers to date have been for case management systems that restrict the providers from whom a Medicaid beneficiary can obtain primary care (332). The implementation of a hospital-only contracting approach, whereby contracts are negotiated with selected hospitals for provision of inpatient care to Medicaid patients, is nevertheless possible. California has recently adopted this approach (226).

The two fundamental variables of hospital contracting are: 1) the rules used to determine which hospitals can serve beneficiaries, and 2) the method used to determine the level of payment for such services. A hospital contracting system could be administered by a negotiated bidding system where the bid price is computed on a per case, per day, or per service basis. Or, the third-party payers could select eligible hospitals on the basis of their per case costs (with or without adjustments for case mix) and either pay a flat prospective rate or continue to reimburse the hospitals on a retrospective cost basis. In either case, by tying a hospital's receipt of revenues to its ability to constrain costs, contracting may encourage hospitals to keep costs low.

The impact of contracting on technology use and on equality of access to medical technology depends to a large extent on the contracting program's design and administration. For example, California's Medicaid program uses a bidding system that encourages hospitals to choose a price for contracted patients that cover short-run, but not long-run, incremental costs of treating those patients. In essence, other classes of payers may subsidize the Medicaid program by bearing more than their share of overhead and other fixed costs. At the time that contracting was instituted in California, hospitals in the State were suffering from very low occupancy rates, a condition which encourages hospitals to offer to treat patients at rates below the long-run incremental costs of treating them (172). If the contracting agency selected low-cost providers and then paid a prospective rate based on fully allocated costs, the cost shift to other payers would be eliminated.

Selected provider contracting can have serious implications regarding the equality of access of beneficiaries to medical technologies. If beneficiaries can receive hospital care only in low-cost hospitals, the availability of certain technologies, particularly newer ones, could be restricted. Moreover, as the revenues of contracting hospitals are held down relative to those with other kinds of patients, the discrepancies could widen over time.

With Medicare accounting for about 35 percent of community hospital revenues nationwide, selected contracting with hospitals by Medicare would probably be highly disruptive and would greatly change the patient mix of hospitals. It would be difficult to contract selectively without turning some hospitals into predominately Medicare hospitals, leaving the others to serve private sector patients. This kind of separation of care by payer class is a necessary condition for the development of a two-class hospital system and would represent the abandonment of the principles of equal access on which Medicare was founded.

INCREASED BENEFICIARY COST-SHARING FOR HOSPITAL SERVICES

Still another approach to affecting the use of medical technologies through hospital payment is to increase beneficiary cost-sharing. One example of this approach was found in the fiscal year 1984 budget request of the Reagan Administration. The Administration proposed an increase in

Medicare beneficiary cost-sharing for inpatient hospital services (224). Under the proposal, the beneficiary would continue to pay a deductible approximately equal to the cost of a day's care but would be responsible for additional payments of 8 percent of the deductible for days 2 to 15 and 5 percent of the deductible for days 16 to 60. In exchange, the beneficiary would no longer be responsible for cost-sharing after 60 days.

Increasing patient cost-sharing has the immediate benefit to the Medicare program of shifting the expenditure burden from Medicare to the beneficiary or other third-party payers. Proponents of increased cost-sharing for inpatient hospital services also contend that patients will have greater incentives to resist unnecessary technology—admissions, long stays, and procedures or services offered as part of the stay. Thus, according to this argument, the Medicare program would benefit from these behavioral influences on the use of medical technology due to increased cost-sharing.

Interim results from the Rand National Health Insurance Study, a well-designed experiment, indicate that the level of patient cost-sharing does influence the use of hospital services (243). This experiment randomly assigned 2,756 families whose members were not older than 61 with incomes under $25,000 (in 1973 dollars) to one of six insurance plans with differing levels of deductibles, coinsurance rates, and upper limits on annual out-of-pocket expenditures. Plans with high levels of coinsurance had lower admission rates per capita than plans with low rates of coinsurance. With coinsurance rates of 50 or 95 percent, hospital admission rates for adults were, respectively, about 60 and 40 percent below those with no cost-sharing. However, the annual expenditure per hospitalized patient showed no consistent or significant relation to the level of cost-sharing. Of the patients admitted to the hospital, 70 percent exceeded their catastrophic limit. Thus, while patient cost-sharing affects hospital admission rates, it appears to be "a poor instrument for affecting costs once patients are admitted" (243).

It should also be noted that the Rand experiment involved cost-sharing for all covered services, not just hospital care. Part of the decline in rates of hospitalization may have been due to a decline in ambulatory care visits that would otherwise have generated a hospital stay. A hospital-only cost-sharing provision with a catastrophic limit on out-of-pocket expenses might not result in the reductions in hospitalization rates experienced in the study. Moreover, applicability of the Rand study to the Medicare program is limited by its inclusion only of a nonelderly population. It is not known whether the elderly would respond to cost-sharing in the same way or to the same degree. Indeed, evidence from this and another short-term study of hospital cost-sharing indicates that cost-sharing's effects on hospital use vary with the patient's age and sex (243,413).

The effect of any beneficiary cost-sharing proposal on the use of medical technology must be considered in the context of a specific method of hospital payment. Under cost-based reimbursement, hospitals had no financial incentive to reduce occupancy rates or the volume of technology use; increasing coinsurance rates, as opposed to increasing deductible amounts, could conceivably have made patients better consumers of care in the hospital. (However, available evidence does not support this contention.) Under the DRG inpatient hospital payment system, hospital administrators have incentives to implement policies that reduce the length of stay and the use of unnecessary ancillary technologies. Increasing hospital coinsurance rates would probably have little additional influence. Increasing the deductible for hospital admissions, on the other hand, might be more consistent with per case payment. In per case payment, the hospital has an incentive to selectively increase the number of admissions and readmissions. At present, the deductible of $356 upon hospitalization covers any readmission within 60 days of the original episode (Social Security Act, secs. 1861(a) and 1813(a)). To the extent that hospital-only cost-sharing can be expected to reduce the rate of hospital admissions in the elderly, requiring a second deductible for rehospitalizations within 60 days would counteract the incentive for hospitals to discharge and readmit patients for elective procedures that could be performed during a single stay.

Whether cost-sharing for inpatient hospital care can moderate the use of hospitals and their technology depends to a large degree on the willingness of Medicare beneficiaries to circumvent cost-sharing by purchasing private supplementary ("Medigap") insurance covering deductibles and coinsurance. In 1976, approximately 63 percent of aged beneficiaries had some form of private supplementary coverage, and 14 percent were eligible for public support, mainly through Medicaid (199). According to one study, most Medigap insurance covers deductibles and coinsurance (217), and joint Medicare/Medicaid beneficiaries have no cost-sharing requirements. These supplementary plans dilute the impact of present cost-sharing provisions.

An increase in Medicare cost-sharing for hospital services would be expected to raise premiums of Medigap policies. The effect of such premium increases on Medigap enrollment has not been studied. Data are available on the correlation between family income and the supplementation of Medicare with private insurance. One study found that, although purchase of supplementary insurance increases with family income, the differences are small across income groups when the availability of public programs, particularly Medicaid, are accounted for (34). Another study found that Medicare families with low incomes were just as likely to purchase private Medigap insurance as families with higher incomes, a finding which may suggest that the elderly are relatively insensitive to premiums in their demand for Medigap coverage (216). If this is the case, increasing hospital deductibles under Medicare would serve mainly as a means of transferring the burden of expenditure from the public to the private sector, with a particularly heavy burden on the near-poor, without substantially altering patterns of hospital use.

CONCLUSIONS

The Medicare program has recently embarked in a new direction in hospital payment with its DRG prospective payment system for inpatient services. The implications of this approach for the use and adoption of medical technology are varied and to some extent uncertain. Much will depend on the way in which the program is implemented and the changes or refinements that may come in the future. The overall DRG price level and the rates of increase permitted over time will have a great deal to do with hospitals' ability to adopt new medical technologies. If, as many have claimed, there is substantial room for increased efficiency in the provision of hospital care, and if the payment level is reasonably generous, DRG payment under Medicare could provide hospitals with substantial surpluses of funds that could be used to provide new technologies and services. If, on the other hand, increases in rates are restrictive or set at a level that reclaims all the cost savings made in the previous years from hospitals, then hospitals would probably find it difficult to finance new cost-raising technologies and services. The results cannot be predicted at this time.

The way in which capital is paid for under DRG payment is a critical issue for medical technology. Permanent continuation of a capital cost pass-through under DRG payment would be inefficient and would ultimately distort hospitals' capital investment decisions, making hospitals too capital intensive. Externally controlled capital payments, on the other hand, are efficient but are difficult to administer effectively or fairly.

Approaches to prospective payment of hospitals other than DRG hospital payment are certainly possible. Innovative prospective payment methods such as per capita hospital payment and areawide global budgeting may hold promise in some areas. Furthermore, the current Medicare law encourages States to experiment with these as part of all-payer systems. In addition, **case-mix classification systems with more desirable properties than DRGs may become available in the future** (343).

HCFA expects to hold statewide systems applying for waivers to the cost-containment standard of DRG payment: for Medicare to join in a State system, the State must provide strong evidence that Medicare's inpatient hospital expenditures will be at least as low as they would be under DRG payment (112). Although the available evidence supports the contention that the hospital cost increases under prospective payment systems implemented by individual States in the mid to late 1970's were lower than those under Medicare's traditional cost-based reimbursement system, there is virtually no evidence on the effects of per case prospective payment using DRGs. Thus, it **is not known how DRGs perform relative to other prospective payment systems or whether the State prospective payment approaches can meet the DRG cost-containment standard.**

Other approaches to the control of hospital costs, including increasing the patient's responsibility for cost-sharing and limiting providers through contracts between Medicare and hospitals, have significant limitations. Patient cost-sharing is not likely to be as effective as desired in altering the patterns of use of hospital technologies because of the patient's relative lack of power and information to make informed decisions about the use of technologies in hospitals and the apparently strong preference of the elderly for supplemental medical insurance regardless of its cost. Finally, although contracting may save program dollars, it represents an abandonment of the principle of assuring beneficiaries freedom of choice of providers on which Medicare was built and forces subsidies of hospital care from other payers.

7.

Medicare Physician Payment and Medical Technology

As the ancients say wisely, have a care of the main chance and look before you leap, for as you sow, you are like to reap.

Samuel Butler

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7.

Medicare Physician Payment and Medical Technology

INTRODUCTION

Although Medicare's method of payment for inpatient hospital services has recently been altered, its charge-based system of payment for physicians' services remains (see ch. 2). Medicare expenditures for physician services continue to grow rapidly, however, and changes in payment are currently being considered. The recent changes in Medicare's system of payment for inpatient hospital services under Part A have been made primarily for the purpose of improving the long-run financial incentives for efficient provision of care. Although one objective of the changes is cost containment, the payment policy does not provide for all savings to accrue to Medicare. Most of the payment changes proposed in the area of physician services under Part B would result in immediate savings to Medicare. By changing physicians' financial incentives to adopt and, especially, use medical technology,[1] however, they would also affect program costs in the future.

This chapter examines methods to change the incentives for the use of medical technologies through Medicare payment for physician services. The chapter discusses physicians' influence on the use of medical technologies and analyzes several methods to enhance cost consciousness among physicians. Then it identifies possible ways that physician payment mechanisms could be used to reduce Part B costs related to the use of medical technologies.

PHYSICIANS AND THE USE OF MEDICAL TECHNOLOGIES

Physicians are the key determinants of the volume and kinds of medical services and technologies provided to patients. Because they control the decisions made and the resources used in providing medical services, physicians can influence the demand for their services. Thus, it is important to consider how physicians behave in their adoption[2] and use of medical technologies and how that behavior is or can be influenced by payment methods and programs in the health care system.

It is generally accepted that the charge-based payment system used by Medicare and other third-party payers provides financial incentives to physicians for the use of "technology-intensive" medical care, and these financial incentives exist even within a primary care field such as general internal medicine (295). Furthermore, the influence of financial incentives is supported by empirical evidence from "natural experiments"[3] in which physicians might be expected to respond to the imposition of restraints on payment for the care they offer by providing larger numbers of "technology-intensive" services.

One natural experiment involved the Economic Stabilization Program (ESP) put in place between 1972 and 1974 to slow the national rate of inflation. ESP imposed both general controls on price increases, including physicians' fees, and administrative controls on the amount Medicare would pay for physicians' services. An examination of the impact of ESP on Medicare payments to California physicians found that growth in billed charges for individual services was successfully slowed by ESP to half that of the pre-1972 rate, and that when controls were lifted in 1974, the rate of increase more than doubled. During the period that ESP was in place, however, physicians' gross payments from Medicare were largely unchanged. The reason was that physicians were able to increase the number of services they provided and to shift to a relatively higher priced mix of services (153).

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[1] As noted in ch. 1, "medical services" is often used interchangeably with "medical technology" in this report.

[2] As noted in ch. 2, there is little empirical evidence related to physicians' adoption of technologies, although it is known that physicians influence hospitals' adoption decisions. Thus, the emphasis in this chapter is on the *use* of technologies.

[3] A "natural experiment" presents changing conditions that can help test a hypothesis.

In the second natural experiment, between 1976 and 1977, all Colorado physicians in similar specialties were grouped together in computing prevailing charges for Medicare reimbursement. Prior to this change, similar specialties had been grouped together, but prevailing charges had been computed for 10 separate regions in the State; urban physicians had had higher prevailing charges than nonurban physicians. After the change to a single statewide prevailing charge for each specialty, urban physicians' prevailing charges were allowed to increase by less than 5 percent, while nonurban physicians had increases of about 20 percent. Subsequently, urban physicians provided more highly intensive services, while nonurban physicians provided less highly intensive services (275). General surgeons who had relative decreases in their reimbursement rates provided greater numbers of surgical services. Declining laboratory reimbursement rates resulted in ordering of more lab tests, and increasing reimbursement rates resulted in ordering of fewer lab tests. Radiology services were not affected (275).

Excessive use of medical technologies is sometimes incorporated into medical practice through the habitual behavior of physicians and because the health care system contains few disincentives for such use. These practices continue even though the ordering physician personally may not benefit financially. Excessive use of medical technologies occurs even within the norms of medical practice and is evident across the spectrum of technologies available to physicians. Some examples follow.

Lengths of stay of patients hospitalized with the same illnesses vary widely across geographic areas, and these differences are explained neither by regional differences in age, sex, or race distribution, nor by regional differences in severity of illness (350).

Between 1972 and 1977, laboratory tests nearly doubled for both hospital and ambulatory care. The costs of hospital laboratory tests increased from $2.2 billion to over $4 billion, and the number of out-of-hospital tests increased from 850 tests to 1,510 tests per 1,000 physician visits (134). Studies on specific tests have confirmed the intuition that much laboratory testing is unrelated to outcome and not used to assist in therapy (232). One study, for example, found a 27-percent increase in the number of laboratory tests but no decline in length of stay for patients hospitalized with diabetic ketoacidosis and pulmonary edema (150). Another study found that blood pressure control did not improve with more and costlier laboratory testing (79).

Laboratory tests are often ignored by the ordering physician, even when the tests are abnormal (90,150,427). And physicians often issue multiple orders for tests to be repeated, the results of which neither provide additional information nor are used by the ordering physician to change therapy (89,209,212,415).

Increases in the number of tests and procedures have contributed to changes in clinical practice that have raised costs (212,298,300). Showstack and colleagues (302) have suggested that increased use plateaus over time, as the use of technologies becomes relatively standardized for individual diagnoses. They therefore suggest that methods to limit increases in use may best be focused on use shortly after technologies are introduced because of the ease with which new technologies can become part of accepted practice and the expansion of the pool of patients in which certain therapies are applied.

Physicians' concerns for their patients' health can lead to physician-initiated visits. An analysis of the magnitude and determinants of physician-initiated visits (286,426) based on a 1977-1978

Photo credit: National Kidney Foundation, Washington, D.C.

The costs of unnecessary and redundant laboratory tests, which have no effect on the type of therapy prescribed or the health outcome of the patient, have contributed to the rise in Medicare expenditures

National Medical Care Expenditure Survey found that physicians initiated 39 percent of all visits in the survey period. Physician-initiated visits increased with patient age and with poorer health status. Although most of the variations in physician-initiated demand could be attributed to medical factors, other factors were also found to influence physician-initiated visits. Greater insurance coverage increased the probability of a physician-initiated visit (but surprisingly, did not affect patient-initiated visits). Greater physician density (i.e., the physician-to-population ratio) also increased the probability of a physician-initiated visit. The analysis concluded, however, that increasing the physician-to-population ratios should not result in large increases in physician-induced demand. The probability of physician-initiated visits also increased with younger physicians, a finding that was attributed to the higher incomes and more established practices of older physicians, who have less financial incentive to initiate visits. The substantial numbers of new, younger physicians expected to enter practice in the coming years, the analysis concluded, may have only temporary impacts on physician-induced demand.

Physicians may also alter their medical practices and change their patterns of technology use because they believe patients may sue them for malpractice if harmed. Thus, defensive medicine can lead to patterns of technology use that increase costs. Two major types of physician behavior have been identified as defensive medicine. The most common type is known as positive defensive medicine and includes such actions as ordering extra tests and procedures, scheduling more followup visits, using more consultations and referring more patients to specialists, telling patients more about risks of procedures or tests, using more consent forms, and hospitalizing more patients (254). Less common is negative defensive medicine, which consists mainly of underutilizing technologies, i.e., not performing certain tests and procedures because of possible risks to the patient, thus forestalling legal actions (370). Another behavior that would fit this category would be the refusal to treat certain patients because of the physician's belief that they may be litigious.

Identifying or measuring defensive medicine is difficult, in part because individual physician decisions may be considered either customary medical practice or defensive medicine, depending on the motives for those decisions. Whether the use of individual tests or procedures constitutes defensive medicine depends on how physicians interpret their reasons for making specific decisions. Not surprisingly, physicians do not always identify (nor do they try to identify) all the components in each clinical decision they make. Some physicians use the information on sensitivity and specificity of diagnostic tests, the prevalence of a particular disease, and other objective information before ordering tests for their patients (101,323). Some physicians consider cost in their decisions. Even physicians who use explicit decisionmaking criteria may not be able to identify the subconscious processes that may modify or override their conscious decision processes. The inability of physicians to specify their reasons for clinical decisions in all cases magnifies the problem of determining which decisions should be classified as defensive medicine.

Published data on the total cost of defensive medicine in the United States are sparse and poorly documented. Estimates of the annual national bill for defensive medicine range from $1.5 billion to $8 billion (239). None of the published estimates refers to a source for these figures.

Evidence of defensive medicine has been based on opinion surveys of physicians, which are necessarily subjective. One early survey concluded that defensive medicine is more likely to *reduce* than to *increase* use of medical technologies (165). Another survey found that fear of malpractice does influence physicians' clinical decisions, especially where positive defensive medicine was used. This study also found that defensive medicine is not practiced extensively (94), a finding which seems to conflict with the results of a survey of a random national sample of more than 4,000 practicing physicians (254). In the survey of 4,000 physicians, 35 percent of the surveyed physicians responded to questions regarding 15 specified practice changes. When asked whether concern over legal liability had induced any of these changes, more than 80 percent checked at least one. For example, 48 percent of the physicians who responded to the survey indicated that they ordered more diagnostic tests, citing fear of malpractice as the reason. Thus, the extent and effects of defensive medicine remain speculative.

METHODS OF ENHANCING COST CONSCIOUSNESS AMONG PHYSICIANS

Several methods of enhancing physicians' awareness of cost-raising behavior have been used selectively in the past and continue to be suggested by policymakers. These methods include education programs, utilization review programs, and second surgical opinion programs. Physician education programs have not been particularly effective in encouraging cost-conscious behavior. Unfortunately, although cost-conscious behavior may have occurred during and immediately following physician participation in education programs, the effect has been quickly lost. Mandatory peer review programs have decreased inappropriate hospital admissions and lengths of stay, but have not been successful in addressing excessive use of tests and procedures. Furthermore, the costs of administering these programs may have exceeded the savings that resulted from them. At a more limited level of peer review, second surgical opinion programs have had an impact on decreasing elective surgical rates, but only when the program has been mandatory, not voluntary.

Physician Education Programs

In 1978, the Association of American Medical Colleges (AAMC) surveyed 119 U.S. medical schools and found that over one-third of them had or had planned programs for teaching health care cost containment to undergraduate students, residents in postgraduate training, or both (175). The 1982-83 AAMC Curriculum Directory, however, lists only 15 medical schools that offered electives in cost containment.

Curriculum development for cost-containment education in medical schools has been suggested by various authors. Some authors have suggested a preclinical and clinical curriculum that would attempt to make physicians aware of the economic consequences of their decisions to use medical technologies, while at the same time assuring quality of care (264). Others have suggested that misuse of tests might be decreased through more medical school courses in microbiology, principles of decisionmaking, cost effectiveness, bioethics, and health economics (101,149). Not only improved physician education, but better incentives for appropriate use of tests and more selective use of automated technology for tests have also been recommended (149). It is important to stress, however, that although these recommendations appear reasonable, they are not founded on actual evidence of effectiveness.

When physicians begin ordering tests and procedures during clinical training, they do not necessarily behave according to their knowledge (144, 232). Attitudes and personality traits are important factors in physicians' clinical decisions. Physician attitudes toward preventive medicine, for example, may be more important than factual knowledge (67).

Several studies have reported a tendency for physicians to underestimate rather than overestimate costs (93,306). Furthermore, the impact of information about costs on physicians' behavior has been mixed. In one experiment, it was found that providing cost information to physicians led to an average reduction in the total cost of tests ordered per patient of almost one-third (78). In another study, two groups of physicians received feedback on costs of X-ray tests and two other groups received information on costs of laboratory tests. X-ray use stayed about the same for all four groups, but laboratory use decreased for the groups receiving feedback on lab tests (66). Peer review feedback alone might not ensure reductions in test usage (66). Long-range results of peer review feedback have also been questionable. Short-term changes in physician test ordering behavior have been demonstrated but have not persisted over the long term (197).

Utilization Review Programs

The purpose of utilization review is to ensure that patients receive appropriate medical services that range from specific diagnostic tests to hospital admission. Since physicians admit and discharge patients and provide and order other medical services, review processes are expected to have an impact on their behavior. The most relevant review programs for Medicare have been the Professional Standards Review Organizations (PSROs).

PSROs, established under the Social Security Amendments of 1972 (Public Law 92-603), were areawide groupings of practicing physicians responsible for reviewing institutional services provided and paid for by Medicare and Medicaid. The purpose of their review was to help ensure that these services were: 1) medically necessary, 2) of a quality that met locally determined professional standards, and 3) provided at the most economical level consistent with quality of care (359). Thus, quality assurance and cost containment were the two purposes of the PSRO program (140,167,313).

PSROs were to accomplish these goals by conducting the following types of evaluations in inpatient hospital settings, long-term care facilities, and ambulatory care settings: 1) utilization review, 2) medical care evaluations, and 3) profile analyses. Utilization reviews were reviews of the necessity of each hospital admission and length of stay. Medical care evaluations were usually audits of patient records to monitor the appropriateness of tests, drugs, and procedures administered to patients, according to locally established criteria. Profile analyses were reviews of patterns of care to identify potential problems. They were intended to assist hospitals in focusing the utilization review and medical care evaluations on their specific problems.

Procedures for the three types of PSRO evaluations were developed in the order listed. By 1980, however, most PSROs had worked mainly with review of inpatient care at short-stay hospitals; they had not worked much with care in long-term care facilities or ambulatory care settings. PSROs could penalize hospitals by withholding Medicare payments, but they have not penalized physicians directly, other than through occasional peer pressure.

The PSRO program was evaluated by the Health Care Financing Administration (HCFA), the General Accounting Office (GAO), and the Congressional Budget Office (CBO). The basic question underlying all three organizations' studies was whether the PSRO program paid for itself. HCFA reported that utilization review in the Medicare program paid for itself in 1977, but the number of hospital days saved per 1,000 Medicare beneficiaries by different PSROs ranged from an 8.75-percent decline to a 1.95-percent increase (365). In 1979, HCFA compared geographic areas with and without PSROs and found a 1.7-percent reduction in days of care in the areas with active review (374). Physician cooperation differed among the regions with and without PSROs, so review was probably not the only cause of the difference. Using the same data but different assumptions and measures of effectiveness, both GAO and CBO disagreed with HCFA's findings and found the savings highly questionable (328, 329,334). HCFA maintained that the appropriate measure was the ratio of reimbursement savings to total program cost, which it calculated to be 1.27 to 1. CBO maintained that the proper measure should have been resource savings instead of reimbursement savings, used different estimates of the effect of PSROs on utilization, made different assumptions on savings on ancillary services, and adjusted the per diem rate used in calculating reimbursement savings. According to CBO, the resource-savings-to-cost ratio was 0.4 to 1. Even if the ratio of reimbursement savings to total program costs were used, however, CBO's ratio (0.9 to 1) was lower than HCFA's because of the different assumptions used (329).

Others have criticized using the costs saved per patient day (even when average variable costs per day were used) instead of marginal costs as the measure of success (50,60). Still others have criticized cost-benefit analyses that compared total costs of the PSRO program with the marginal benefits of PSRO review over claims review by intermediaries (313). In addition, the use and cost of alternative forms of care for patients with shorter lengths of stay are usually ignored in analyses (60). Yet another problem is the fact that quality improvements resulting from PSRO review activities were not measured and considered in the evaluations (202), although HCFA did distribute a quality review studies policy to PSROs in 1980 (376).

More specific evaluations of individual PSROs and PSRO-type organizations were conducted in many parts of the country (50,98). The studies reported little or no cost savings, and in those studies where cost effects were observed, no control groups had been assigned, so the cause of any cost savings found could not be conclusively attributed to the review programs (60,98). In one hospital study, while length of stay and average charges per patient generally decreased following institution of PSRO review, the decrease did not result in overall cost savings to Medicare and Medicaid (425).

Following years of budget cuts and uncertainty over their continuation, PSROs were replaced statutorily in 1982 by utilization and quality control peer review organizations (PROs) in the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248). The Social Security Amendments of 1983 (Public Law 98-21) provided funding for PROs through Part A of Medicare and made PRO contracts a condition of participation for hospital payment. PSRO areas will be consolidated into PRO regions. The PROs will be contract organizations that will set objectives to meet quality assurance and cost-containment goals at the beginning of each 2-year contract period and subsequently be evaluated on the basis of those objectives. PRO functions will include review of the validity of diagnostic information provided by hospitals (Diagnosis Related Group verification); review of the completeness, adequacy, and quality of care provided to inpatients; and review of the appropriateness of hospital admissions and discharges.

Evaluations of types of utilization review other than that performed by PSROs have been attempted. Few studies of ancillary service review focus on the review's effectiveness, but several studies have shown that ancillary service review may not have the desired effect of reducing the number of tests and procedures used. One of the basic reasons for this result is that it is physicians, and not hospital administrators, who admit patients to hospitals, order diagnostic tests and therapeutic procedures for inpatients, and discharge patients from hospitals, while the financial incentives or other requirements are often aimed at hospital administrators. There is also wide variation in ordering of ancillary services by physicians (98).

Utilization review has also been performed in nonhospital settings, although to a limited extent. Until recently, cost problems for the Medicare program were not as obvious for ambulatory services as for inpatient hospital care, because the Part B program, which covers ambulatory services, includes patient copayments and deductibles. PSRO demonstration projects in which ambulatory care was reviewed concentrated on the Medicaid population, for whom the Federal and State governments pay the entire ambulatory care bill. Reviews of multiple ambulatory care facilities have been inconclusive (252).

Second Surgical Opinion Programs

The institution of second surgical opinion programs for elective procedures represents another approach to enhancing cost consciousness among physicians and containing costs in both private and public sector health insurance programs. Although some second surgical opinion programs maintain that their purpose is to better inform patients so that they can make appropriate decisions, the major purpose of such programs is to reduce the numbers of unnecessary surgical operations.

Insurance groups were among the first to become interested in the potential cost savings of second surgical opinion programs. Members of several unions in New York City have participated in mandatory and voluntary second opinion programs conducted by Cornell University Medical School/New York Hospital since 1972 (123,218, 219,220,221,288). Several Blue Cross and Blue Shield plans have voluntary second surgical opinion programs (225). At least one commercial insurance company, The Prudential Co., has used a mandatory program (4). In addition, six State Medicaid programs (Massachusetts, Michigan, Missouri, New Jersey, Washington, and Wisconsin) use second surgical opinion programs to control costs (281). The Medicare program itself has experimented with voluntary second surgical opinion demonstration projects in Detroit and New York City (127).

Although second surgical opinion programs differ in detail, they can be best distinguished by their mandatory or voluntary nature. Mandatory programs generally require patients to consult with a board-certified surgeon, often from a panel designated by the third-party payer, before elective surgery. If patients do not seek second opinions, they may not receive insurance benefits for those procedures (in some programs, however, patients still retain the right to receive insurance benefits for the surgery even if the second opinion contradicts the original recommendation for surgery). Consultation fees are usually covered by the payer when the second opinions are mandatory. Mandatory programs have averaged 18 to 20 percent nonconfirmed opinions (225).

Voluntary programs make available lists of board-certified surgeons but do not require consultation in order for patients to receive reimbursement for surgical procedures. Sometimes these programs will make the appointments for the patients' second opinion consultations, and they, too, usually cover the consultant's fees. Few patients (about 2 percent) participate in these voluntary programs. Those who do are a self-selected sample and are not necessarily representative of the group. Not surprisingly, patients in voluntary programs get more nonconfirming second opinions than do patients in mandatory programs. The national average nonconfirmation rate in Blue Cross and Blue Shield plans' voluntary program was 30 percent and one Ohio plan had a 42-percent nonconfirmation rate (225).

HCFA has sponsored demonstration projects to test whether Medicare beneficiaries would use a voluntary second opinion program if they did not have to pay any out-of-pocket expenses. Two sites were chosen, and contracts were awarded to Blue Cross and Blue Shield of Michigan and of Greater New York. Both of these projects began in 1978 and ran for 3 years. Participation rates were very low. In New York, 1.2 percent of Medicare beneficiaries who had surgery participated; in Michigan, 0.3 percent participated. HCFA estimated that the maximum reduction in surgery rates was 12 percent, and with the low participation rates, the maximum reduction in the number of surgical procedures would be less than 0.5 percent for Medicare beneficiaries (127).

Mandatory second surgical opinion programs have usually been found to have greater cost savings than expenditures. In a study at Cornell/New York Hospital, $2.63 was saved for each $1.00 spent on the program (288). The Massachusetts Medicaid program has been estimated to save $3.90 for each $1.00 spent, including the "sentinel" effect (the change in frequency of physician recommendations for surgery when they are aware that their patients will need a second opinion) (213). Another study of the Massachusetts Medicaid mandatory program, however, examined one procedure from other areas of Massachusetts and found that "speculative, simple benefit-cost analysis" yielded ratios of 2.27, 1.11 and 0.79, depending on the assumptions made and not including the sentinel effect (133).

Voluntary programs, on the other hand, have high administrative costs relative to the low participation rates. Even though nonconfirmation rates are higher in voluntary programs, there is little potential for savings because of the low numbers of patients getting second opinions.

The use of second opinion programs, although assumed to decrease surgical rates, might increase them. Researchers in both mandatory and voluntary programs have indicated that patients tend to follow the second opinion consultant's recommendation (127,218). Since confirming second opinions outnumber nonconfirming second opinions, some of the patients with confirming opinions might decide in favor of surgery they might not have had without the second opinion (48).

CHANGES IN PHYSICIAN PAYMENT

The use of Medicare's physician payment method to contain Part B costs related to medical technology adoption and use consists of two approaches:

- imposing restraints on the amount and changing the method of payment to physicians, and
- requiring Medicare beneficiaries to assume more responsibility for their health care costs, either through increases in patient cost-sharing or reductions in the types of benefits covered.

Although either approach could result in cost savings for the Medicare program, each would have different effects on the use of medical technologies and on access to medical care by Medicare beneficiaries.

Changes in the Amount and Methods of Physician Payment

Restricting payment to physicians means the adoption of fee schedules or similar restrictions on the level of payment physicians will receive from Medicare. The inflationary nature of the "reasonable charge" criterion by which physicians are reimbursed by Medicare has been dampened somewhat by the imposition of the Medicare Economic Index, which limits the rate of increase in physicians' fees to the rate of increase in their costs (see ch. 2). Further controls on physician payment, such as indexing fee increases to the Consumer Price Index (CPI) or developing a system of fee schedules, would help to save some program costs and are discussed below. Such changes, however, would leave three problems unaddressed: 1) as long as Medicare's voluntary assignment policy continues, physicians can attempt to recoup their unreimbursed charges from patients; 2) because physicians would still determine the price they will charge (as opposed to what portion of that price Medicare will pay) and because no rational mechanism to set prices for new procedures exists, inflation in medical prices will continue; and 3) even if physician payment is limited, physicians may create demand for their services. Currently, physicians can respond to a reduction in the amount that Medicare will pay by refusing to accept assignment. If a physician refuses assignment, Medicare reimburses the beneficiary rather than paying the physician directly, but the physician can still anticipate payment.

Limits on Reasonable Charges

To slow growth in reasonable charges for physicians' services, indexes other than the Medicare Economic Index could be used. One of these is the CPI, which is projected to grow at a lower rate than the Medicare Economic Index (330). Reasonable charge levels could also be frozen temporarily and/or limited to modest yearly percent increases (412).

Reasonable charges could also be selectively reduced. Hourly reimbursement rates in 1978, for example, after standardization for variations in the complexity of different procedures, ranged from $40 for a general practitioner to $200 for surgical specialists (174). Thus, allowed charges for surgical procedures might be reduced by a specified percentage (e.g., 10 percent) (330).

Fee Schedules

Fee schedules are set amounts of payment for particular services. Indeed, indexing the growth in reasonable charges to the Medicare Economic Index is slowly leading to a de facto fee schedule, but the base rate upon which allowable increases are calculated retains the historical specialty and geographic differences in fee levels that have developed under the current system of payment. Fee schedules could be constrained on this historical basis of current fee levels or recalibrated on the basis of costs. Historical fee levels for existing technologies and services could be retained—with controls on future increases—and cost-based fee levels developed for new technologies and services as they are adopted and disseminated. But putting new procedures on a cost basis and leaving old procedures on a fee basis might encourage retention of older, less effective technologies.

The adoption of fee schedules to achieve limited cost containment and provide incentives for appropriate technology use within the confines of the Part B program could be approached in a number of ways.

First, de facto fee schedules could occur by simply freezing current allowed charges, by continuing use of the Medicare Economic Index, by replacing the Medicare Economic Index with a less inflationary index such as the CPI or by imposing arbitrary limits (e.g., 5 percent) on the growth of reasonable charges.

Second, selected specialties could be targeted for fee schedules, such as by imposing a 10-percent reduction in fees for surgical procedures (330). Alternatively, fee schedules could also be selectively or incrementally applied, perhaps starting with inpatient surgical services (330), which comprise about 25 percent of physician payment under Part B (222). Inpatient surgical services would also be a logical starting point to complement the Diagnosis Related Group (DRG) system of payment for hospital care under Part A.

Another possibility relates to ways to encourage higher assignment rates without increasing costs. A study of changes in Medicare reimbursement rates and their relationship to changes in assignment rates has led to the suggestion that increasing reimbursement for medical services would lead to an increase in assignment rates, but that decreasing reimbursement rates for surgical, laboratory, and radiological services would not lead to significant decreases in assignment rates (276). The existing fee and price system provides financial incentives for the use of "technology-intensive" medical care (295). Still another possibility, therefore, is to initiate movement toward an overall review of the relative values of all procedures and revision of the fee system, to value "cognitive" services more equally with technology-intensive services.

Third, fee schedules could be more broadly applied, for example, in the conversion of physician payment to a parallel DRG-based system. This approach could be limited to inpatient and a few other (e.g., skilled nursing facility) physician services only, extended to ambulatory care for DRG-related services, or extended to all physicians' services. In other words, physician payment could be included in the current DRG system for inpatient care, or a fee schedule might be devised that would consist of capitated payments for all services associated with a particular diagnosis.

Whatever the approach to fee schedules, administrative changes in the coding system that would have to precede specific changes in methods of payment may of themselves lead to significant cost savings, whether or not they are subsequently used to implement fee schedule changes. The ease with which physicians can use medical technologies is in part a function of the present coding system that is used by Medicare to identify and pay for medical services. That coding system has developed in part in response to the payment policies implemented under the Medicare program.

Procedure codes are used to determine Medicare's reasonable charges. At Medicare's inception, Medicare providers could use any coding system on their Part B claims and could change codes at any time. In 1979, providers were required to continue with whatever coding system they were then using. Providers were subsequently required to use a standardized coding scheme for Part B, the HCFA Common Procedure Coding System (HCPCS), which all providers are required to use by the end of fiscal year 1985. In HCPCS, coding for physicians' services is identical to the American Medical Association's Current Procedural Terminology, 4th Edition (CPT4). The CPT4 code is augmented with compatible codes for nonphysician services, such as laboratory services, radiology services, durable medical equipment, orthodontic services, chiropractic services, and dental services. Coding for Part B remains completely different from Part A coding, as hospitals have been using the International Classification of Diseases (ICDA, Adapted for use in the United States), which they consider more appropriate for hospitals (19).

In 1966, at the time of the implementation of Medicare, the first Current Procedural Terminology (CPT1) contained 2,084 separate procedures. By 1969, the second edition (CPT2) contained 3,440, up 65 percent; and by 1977, CPT4 contained 6,132 procedures, an increase of 78 percent over the 1969 edition and an increase of almost 200 percent in 10 years (228).

The large numbers of procedures from which to choose not only make it easier for physicians to bill for their more expensive services, but also increase the possibility that physicians will inadvertently bill for the wrong procedures. Thus, for example, in an analysis of two types of operations performed on Medicare patients—cholecystectomy (removal of the gallbladder) and total hip replacement—it was found that different members of the surgical team frequently billed for entirely different operations. The chief surgeon and the assisting surgeon billed for entirely different operations 19 percent of the time. The surgeon and anesthesiologist disagreed even more, in 40 percent of the gallbladder operations and in 55 percent of the total hip replacements (228).

Similar problems have been found with hospital discharge data. In two studies of the reliability of hospital discharge data (236,237), two types of data discrepancies were found: 1) "ordering" discrepancies, reflecting problems in determining which of several diagnoses or procedures should be regarded as the principal one, and 2) coding discrepancies, reflecting errors in assigning a diagnosis or procedure code number. As a result, the discharge data were reliable in only 66.8 to 77.5 percent of the cases in the first study (236), and in only 59.1 to 64.1 percent of the cases in the second study, which examined data on Medicare beneficiaries (237). In both studies, the correct diagnostic code was a matter of judgment in about 5 percent of the cases. And in the Medicare study, in 70 percent of the cases in which discrepancies were found, the data on principal diagnosis included in the Medicare claim did not accurately reflect the patient's condition.

Several groups of physicians have made attempts to create coding systems for common diagnoses encountered in office-based practice. These include the United States Modification of the Royal College of General Practitioners Classification (567 categories), the Canadian Modification of the International Classification of Health Problems in Primary Care (ICHPPC) (371 categories), and ICHPPC-2 (362 categories) (294).

Thus, it appears that proliferation of codes and their categories satisfies neither physicians nor those concerned with the use of these codes for payment and other purposes. A smaller number of billing packages could be constructed—numbering in the hundreds, not in the thousands, and perhaps mirroring hospital-based DRGs—which would bear a more reasonable relationship to the services actually provided by physicians.

Repackaging of physicians' services could concentrate on office visit and special procedure packages. Office visit packages could combine visits and ancillary tests instead of paying for them separately. Present codes could be collapsed for surgical procedures as well as for office visits, and an all-inclusive bill submitted by one physician (e.g., the chief surgeon) could avoid the problem of inconsistent billing by members of the surgical team (228).

Special procedure packages, the inpatient analog to office visit packages, could be defined narrowly to include just specialist services or broadly to include all inpatient and nursing home costs as well. The more narrow packages for special procedures, a more feasible starting point, could be used to group all inpatient physicians' services, i.e., not only specialist services but also services provided by the patient's primary physician for inpatient care (228).

Assignment

Physicians at present can decide whether to accept assignment on a claim-by-claim basis. When physicians refuse assignment, they are released from their obligation not to demand the difference between their billed and allowed charges from their Medicare patients.

Assignment rates fell from a high of about 60 percent of claims in the early years of Medicare to approximately 50 percent in the mid-1970's and have remained near 50 percent since then (80,118). These rates include claims from beneficiaries receiving both Medicare and Medicaid benefits for whom assignment is mandatory and who comprise about 10 percent of the total. Thus, the assignment rate for services where physicians have discretion in accepting assignment is about 40 percent.

Assignment rates vary greatly by State, from a high of 83.9 percent of services for the aged in Rhode Island, to a low of 19.7 percent in Oregon in 1978 (222). Assignment rates also vary by medical specialty. The highest assignment rates (about 60 percent) are in the hospital-based specialties of pathology and radiology (222). This situation may change, however, because pathologists and radiologists are now paid 80 percent of reasonable charges (until 1983, they received 100 percent).

As long as Medicare pays for nonassigned care, cost shifting to patients is likely to occur, because physicians can attempt to collect the unreimbursed portion of their bills from their patients. There are several possible methods of penalizing physicians for not accepting assignment. One option is for Medicare to institute a mandatory assignment policy in which no payment would be made for nonassigned care (228). A mandatory assignment policy would solve the problem of cost shifting to beneficiaries, but at issue is whether a substantial number of physicians currently treating Medicare patients would refuse to participate under mandatory assignment.

In a 1976 national survey, over two-thirds of primary care specialty physicians indicated that they would take no Medicare patients on assignment if assignment were mandatory. The greatest influence on the choice was the physician's current assignment rate—physicians with higher assignment rates were more likely to choose to accept assignment rather than not to participate. If assignment were mandatory, assignment rates were predicted to decline about 10 percent nationwide, and the total supply of assigned visits to decline by almost 6 percent. Assigned visits were predicted to increase 11 percent for general practitioners but to decrease 12 to 25 percent for general surgeons, internists, and obstetrician-gynecologists. Despite the survey results, the investigators concluded that few physicians could probably afford to give up their Medicare clientele totally, despite their threats (228).

More recent information supports the idea that physicians would find it difficult to cease treating Medicare patients. The number of physicians who treat Medicare patients is large. In 1982, 87 percent of active physicians treated some Medicare patients, and 80 percent of these physicians accepted assignment on some of these patients (1). In a 1981 survey of physicians maintaining office practices, nearly 15 percent of their patient visits were funded by Medicare. Cardiology, internal medicine, urology, gastroenterology and several surgical subspecialties had levels of Medicare-funded visits well above the average. Moreover, while 23 percent of visits to all of the surveyed physicians were by patients 65 years and older, 47 percent of the visits to cardiologists were by patients 65 years and older; for internists, the figure was 41 percent; for urologists, 39 percent; and for gastroenterologists, it was 36 percent (178).

Physicians also tend to accept assignment in proportion to the size of their Medicare patients' bills, the assignment rate rising to as high as 79 percent for bills over $2,500 for internists and 73 percent for general surgeons (222). If faced with mandatory assignment, the potential loss of income from their more expensive services may be enough to offset whatever misgivings they might have over accepting assignment for all Medicare claims.

Another possible influence on assignment choices is the rapid growth in the number of physicians, largely due to Federal policies beginning about the time Medicare and Medicaid were enacted in the mid-1960's. As a result of these policies, the supply of physicians has grown much faster than the population has. There were 165.5 physicians per 100,000 population in 1974, increasing to 193.1/100,000 in 1980, and projected at 213.8/100,000 in 1985 and 231.3/100,000 in 1990 (346). Increases in the number of physicians relative to population growth have been positively correlated with increased assignment rates among general practitioners and internists, perhaps indicating that increased competition induced physicians to accept assignment on more claims to attract patients (276).

Medicare is, therefore, already an important contributor to physicians' incomes and will become even more important to physicians' practices as the size of the aged population continues to increase. Thus, existing conditions and future trends make it likely that most physicians would continue to treat Medicare patients.

One option besides mandatory assignment is for Medicare to pay for nonassigned claims but at lesser rates. Nonassignment could be discouraged by discounting the physician's charge on nonassigned bills in addition to the 20 percent coinsurance. This could be accomplished either by reducing the allowed charges for nonassigned care or by increasing the coinsurance rate (e.g., to 50 percent) (228). A variation of this option is to allow slower growth in allowed charges for nonassigned care (330).

Changing assignment policy is closely linked to changes in physician payment. If further controls are placed on the rate of payment to physicians while assignment policy is left unchanged, it is likely that the bulk of program savings will be borne by beneficiaries if there is no change in medical technology use. Even though Medicare would reimburse the beneficiary and not pay physicians directly when the physicians refuse assignment, physicians could still anticipate payment, subject only to delayed payments and bad debts. Thus, in the absence of a change to mandatory assignment, policies aimed at physicians ultimately would be felt most by Medicare's beneficiaries.

Therefore, no matter whether program savings come initially from reduced physician payment levels or increased cost-sharing by beneficiaries, in the absence of mandatory assignment, most Medicare Part B savings will still ultimately come at the expense of beneficiaries.

Discussion of Physician Payment Changes

Policies that place further limits on Medicare's allowable charges may themselves lead to further distinctions between physicians who treat Medicare patients and those who do not. The price differential between what Medicare will pay and what physicians charge their non-Medicare patients may become large enough that many physicians may refuse to treat Medicare patients. The alternative is that most physicians would continue to treat Medicare patients. However, most program savings would again ultimately be borne by beneficiaries, because beneficiaries would still be liable for the difference between allowed and billed charges under current assignment policy.

When any payment system is changed so that it changes the incentives to provide care, reviews of the appropriateness of the care provided are generally regarded as necessary for quality assurance. As noted earlier, most PSROs were never able to progress substantially beyond reviews of hospital admissions and continued stays, nor did they include reviews of ancillary and physicians' services (109). And review activities have not included extended-care facilities or ambulatory care. PSROs were statutorily replaced by PROs in 1982 (Public Law 97-248). While it is too early to tell what kinds of review activities these new organizations will undertake, it is doubtful that many PROs will begin to review physician and ancillary services soon. Given the difficulties in assessing what is necessary medical care at the service-by-service level, it is even more doubtful that PRO reviews will be extended any time soon to ambulatory medical care.

Another possible review activity is second surgical opinions. The Inspector General of the Department of Health and Human Services recommended that HCFA initiate legislation on mandatory second surgical opinion programs for Medicare and Medicaid (44). The types of surgery for which second opinions would be mandatory would be specified, and beneficiary copayments and deductibles would be waived for the second surgical consultations. HCFA has responded that these actions would be premature because of limited research on mandatory second surgical opinion programs and because of what HCFA considers questionable cost estimates made by the Inspector General (44).

Increased Beneficiary Cost-Sharing

Cost shifting to beneficiaries is expected to give beneficiaries increased incentives to be more prudent in seeking medical care. The expectation is not only for patients to reduce their use of physicians' services (199,243,299), but also that physicians would reduce prices (307,309). Greater selectivity by patients in seeking medical care, resulting in fewer visits to physicians, it is hoped, will force physicians to compete by lowering their prices.

It is important to note that different methods of cost shifting to Medicare beneficiaries can have different effects. Increasing Part B premiums should have little or no effect on the demand for services, because the increased cost is incurred regardless of whether beneficiaries reduce their demand for services. Raising premiums is an insurance mechanism for spreading the costs across Part B's entire beneficiary population. Increasing the deductible and coinsurance, on the other hand, may reduce demand, because more costs are incurred by the beneficiary as more services are used.

In considering increases in cost-sharing by Medicare beneficiaries, it is important to recognize that the elderly already have more out-of-pocket expenses than the young. The results of 1977 and 1978 interviews with 14,000 households indicate that annual out-of-pocket expenses increased steadily by age, from $97/year for patients under 6 years of age, to $295/year for patients age 55 to 64, and to $326/year for those over 65 after Medicare's contribution (396).

Another important point is that the Medicare population is not homogeneous in its use of medical services. About two-thirds of elderly beneficiaries use their Part B insurance in a given year (339). But less than one-fifth of beneficiaries account for nearly 90 percent of costs, and these high users of medical services tend to remain high users over time (215). Whether these high users are consuming large amounts of unnecessary services is not known, but the answer is crucial to the question of whether increased cost-sharing would simply shift costs from the Part B program to beneficiaries, or whether it would also lead to reduction of unnecessary technology use.

Premiums

As noted in chapter 2, beneficiary expenses under Part B are premiums, deductibles, and coinsurance. At the outset of the Medicare program, premiums financed half of Part B program costs. By 1978, following amendments limiting Part B premium increases to no more than the percentage increase in social security cash benefits, however, the percentage contribution of premiums to Part B costs had dropped below 25 percent (134). Under the Omnibus Budget Reconciliation Act of 1981 (Public Law 97-35), the limitation on Part B premium increases was suspended for a 1-year period between July 1, 1983, and July 1, 1984. During this period, premiums were to be increased so that they met 25 percent of Part B costs. However, the Social Security Amendments of 1983 (Public Law 98-21) delayed the start of the suspension period to January 1, 1984. Thus, premiums rose to $13.10/month on July 1, 1983, and rose again to $14.60/month on January 1, 1984. The previous method of calculating premiums is expected to resume on January 1, 1985.

In its fiscal year 1984 budget proposals, the Reagan Administration recommended increasing premiums until they reached 35 percent of Part B program costs by 1988 (412). CBO identified two similar options: 1) increasing premiums to 30 percent of costs; or 2) limiting the premium increase to higher income elderly, with a cutoff point in income at $20,000/year (330).

Most of the elderly participants in Medicare Part B have some form of supplemental "Medigap" private insurance. In 1976, 63 percent had private insurance, and another 14 percent had Medicaid or some other public supplemental insurance (199). CBO hypothesizes that additional medical services used as the result of extra first dollar coverage by Medigap policies will cost the Medicare program $3.2 billion in 1984, most of which CBO estimates could be recovered by a 30-percent premium tax on any Medigap policy that pays any part of the first $1,000 of Medicare cost-sharing (330).

The Social Security Advisory Council to the Secretary of the Department of Health and Human Services has recommended that Part B premiums be doubled and the extra revenues be used to finance changes in Medicare's Hospital Insurance program. Under the Social Security Advisory Council's proposal, Medicare patients would have no limit on the number of days of hospital care each year after paying an initial deductible of $350 for the first day, plus a second deductible of $350 if additional hospitalizations occur.[4] Out-of-pocket costs for Part B would be limited to $200 per year, a limit which would decrease the demand for commercial Medigap policies, because premiums for these policies cost from $300 to $800 per year (372). For protection against the $200 deductible and for services not covered by Medicare, however, some demand for supplemental insurance should continue.

Part B premiums could be varied to reflect local costs. The reasoning follows analyses of plans for implementing a voucher system.[5] It has been proposed in those plans that the value of the voucher follow average reimbursements at the county or State level. Under such proposals, differences in the value of the voucher are meant to reduce the intermarket subsidies that result from large variations in per capita expenditures for hospital care and reimbursement for Medicare and private insurance enrollees. Otherwise, in some low cost markets, the value of the voucher would be more than current per capita reimbursement rates, and total costs would rise. If the price of health insurance were adjusted to reflect local market conditions, more competition might result (424).

Following that theory, Part B premiums could be similarly adjusted, with higher premiums for areas with higher program costs. For example, because Part B participants already are subsidized by general revenues (such revenues cover 75 percent of current Part B costs), the lowest premiums could be set at the current rate. While this change would relate premium costs more closely with local medical costs, it would not be expected to lead to more competition. Beneficiaries would still have only one choice of an insurance plan and would not have the opportunity to shop among competing insurance plans as would be the case under a voucher system.

Deductibles

The current deductible, the amount Medicare beneficiaries pay before Part B insurance is activated, is $75 per year. The deductible could be indexed to the Medicare Economic Index so that the deductible would increase in pace with medical costs (412). It could, of course, be set at any other level.

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[4] The purpose in requiring the second deductible is to moderate the financial incentive under DRG hospital payment to increase admissions. See ch. 6 for more information.

[5] A voucher is an entitlement of fixed value for the purchase of health insurance. For a discussion of vouchers, see ch. 8.

Unlike the premium, the deductible is related to initial use of services. In Medicare's elderly population, however, many people have chronic diseases and require continued access to care. For such a population, the deductible may often not be a deterrent to seek care, but a financial hurdle to overcome with each new calendar year. Thus, increasing the Part B deductible would shift costs from the Medicare program to its beneficiaries and might not result in any significant reduction in the demand for medical technologies.

Coinsurance

Coinsurance raises financial barriers to the use of medical services each time such services are sought. Thus, increasing Part B coinsurance requirements might reduce demand, because costs would be related to the amount of services used. However, Part B beneficiaries already have a coinsurance requirement of 20 percent, and for nonassigned care, beneficiaries incur additional liability for the difference between allowed and billed charges. Thus, one issue is the amount of additional coinsurance requirements that might be reasonably imposed, and whether those additional beneficiary costs would be accompanied by a significant reduction in demand.

In the past, suggestions to change Medicare's coinsurance requirements have been focused on Part A, where coinsurance is currently activated only after 60 days of hospitalization for a particular illness. Together with the coinsurance of 20 percent of allowed charges under Part B, imposing hospital coinsurance raises concern that out-of-pocket expenses could be substantial for hospitalized beneficiaries. Thus, for example, one CBO proposal to impose hospital coinsurance for the next 29 days after the day of admission (on which there is a deductible equal to the average cost of 1 day's hospitalization) also includes coverage of all charges after the first 30 days and a cap of $2,000 on total out-of-pocket costs for both Parts A and B for beneficiaries with annual incomes below $20,000 (330).

Discussion of Beneficiary Cost-Sharing

Although a significant amount of cost-sharing is possible through changes in the Part B program, the likelihood of cost containment from such changes is limited at best. If significant cost containment occurs, it may come primarily at the expense of reduced access to medical care for Medicare's beneficiaries. **And while reduced access includes a reduction in the provision of excessive technology use, it also implies a reduction in the provision of necessary and appropriate medical care.**

Of the three types of direct financial liability incurred by beneficiaries participating in Part B—premiums, deductibles, and coinsurance (a fourth liability is the difference in billed and allowed charges for nonassigned care)—changes in premiums have the greatest potential for reducing Medicare program costs. The extra revenues from the Social Security Advisory Council's proposal to double Part B premiums were projected to allow unlimited hospitalization after an initial deductible for each hospitalization, as well as to limit out-of-pocket costs in Part B to $200 per year. The $200 per year limit on out-of-pocket costs, in turn, was expected to make commercial Medigap policies less attractive (372). Premiums, however, are insurance mechanisms for spreading the risk of the costs of illness, but are not particularly relevant in affecting behavior related to medical technology use. This observation is particularly applicable with respect to the Part B program, where premiums purchase a single insurance policy—i.e., beneficiaries have no choice in the types of coverage they might purchase (as they would in the case of a voucher system). Regardless of their prudence or excess in seeking medical services, beneficiaries receive no feedback in terms of the medical costs they incur. Furthermore, premiums are deducted from Medicare beneficiaries' Social Security checks before the checks are issued, so beneficiaries' awareness of the relationship between premium levels and the costs of medical care is even less than it might be otherwise.

CBO hypothesized that, of all the Medicare-specific proposals to contain program costs, a tax on premiums for supplemental Medigap insurance would result in the greatest savings (330). Currently, all persons who purchase health insurance enjoy a tax subsidy, and elimination of that subsidy is a crucial element of proposals to increase competition in health care by making consumers more cost conscious (355). Despite the economic rationale, however, proposals that increase cost-sharing for Medicare beneficiaries and that also penalize them alone for seeking additional insurance against this greater cost-sharing by taxing their supplemental policies would be widely regarded as discriminatory. Furthermore, the elderly population has greater medical needs and more out-of-pocket expenses than the younger population (396). Thus, a tax on supplemental insurance, while leaving the tax subsidy on general health insurance intact, not only would be discriminatory but also would be imposed on a class of persons who have the greatest need for medical care.

Finally, while a tax on supplemental insurance has been projected as resulting in the greatest savings of the proposals identified (330), the projected savings are also the most hypothetical. In addition to premium tax receipts, the bulk of the savings are expected from a reduction in the use of Medicare-reimbursed medical services by beneficiaries who drop their Medigap coverage. Although such a reduction in use can be expected, quantifying the effect on the Medicare-reimbursed portion of these services is a tenuous exercise.

Deductibles and coinsurance are methods with more promise than premiums for changing physician and patient behavior and thus containing long-term Medicare costs, but even changes in these areas have limited applicability in the Part B program.

A large deductible may be more appropriate for hospitalization than for ambulatory care, particularly for the Medicare population. Because of the higher prevalence of chronic conditions among the elderly than among the younger population, maintenance therapy for elderly people is more essential. Therefore, increasing the Part B deductible would have a predominantly cost-shifting effect without a proportional decrease in demand for services.

Coinsurance has the effect of raising financial barriers each time medical services are sought. Thus, it would have a more significant effect on the demand for ambulatory care than a deductible would. However, Medicare beneficiaries already have a 20-percent coinsurance liability under Part B, and for nonassigned care, the coinsurance is higher. Together with other out-of-pocket expenses, less than half of the health expenditures by the average elderly Medicare beneficiary was covered by Medicare Parts A and B in 1978 (203).

Substantial increases in beneficiary cost-sharing would likely come at the expense of reduced access for Medicare beneficiaries. While reduced access would be less likely or of less magnitude with incremental increases, the effect would probably be a simple shift of costs from the program to beneficiaries. This effect would occur because marginal changes in the Part B program cannot be expected to substantially alter the limited incentives for cost containment that are inherent in the Part B program.

CONCLUSIONS

Strategies for changing the incentives for physicians to provide medical technologies under Medicare's Part B have substantial limitations. These limitations fall into two categories.

First, short-term Medicare *program* savings can be achieved, but these savings are likely to come primarily at the expense of beneficiaries and would not necessarily reduce *excessive* care. If payment limitations are imposed on physicians' services, beneficiaries would be affected either indirectly through cost shifting from physicians to beneficiaries or directly through increased cost-sharing. A substantial increase in cost-sharing through increased coinsurance *might* reduce demand significantly, but two factors argue against this approach: 1) there is already a coinsurance of 20 percent; and 2) further significant increases (e.g., up to 50 percent) might reduce beneficiaries' access to necessary medical care.

Even if these Medicare-specific approaches to containing Part B costs resulted in an acceptable allocation of costs between beneficiaries and physicians, the second limitation is that the gap between fees paid through Medicare and those collected from non-Medicare patients would continue to widen. In 1978, the percent reduction of the average total billed charge per service used to calculate the average Medicare-allowed charge was 20.3 percent, up from 18.7 percent just 3 years earlier in 1975 (222). Further increases in the difference between billed and allowed charges, which could be expected if additional restraints were placed on physician fees under Medicare, again raises the issue of reduced access for Medicare beneficiaries. Equalizing fees for all patients would solve the access problem and could be accomplished either by raising public fees or by imposing a fee schedule on all physicians' services, public and private. Raising public fees would lead to higher charges, but fee controls alone, under the current method of billing based on existing diagnostic and procedure codes, may not be enough to control expenditures for medical technologies or to provide incentives for the provision of the most cost-effective technologies. Thus, there is still a need for methods other than changes in payment, such as utilization review to monitor and evaluate the quantity, mix, and quality of the medical technologies provided (170), or more focused reviews, such as with second surgical opinion programs.

8.

Alternative Approaches to Changing Incentives for Medical Technology Adoption and Use

> When society requires to be rebuilt, there is no use in attempting to rebuild it on the old plan.
>
> —*John Stuart Mill*

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8.

Alternative Approaches to Changing Incentives for Medical Technology Adoption and Use

INTRODUCTION

The strategies in previous chapters have focused on changes in Medicare payment methods—changes in coverage policy for individual technologies and changes in hospital and physician payment. This chapter explores policy mechanisms other than payment that could be instituted by Medicare in order to foster the appropriate adoption and use of medical technologies and ultimately save costs. Such mechanisms include changes that must involve the general health care system but that Medicare could encourage or embrace and changes in the structure of the Medicare program itself. For discussion in this chapter, the mechanisms are divided into two broad categories: 1) methods to foster competitive behavior by providers, and 2) administrative changes in Medicare.

It is generally believed that costs to the Medicare program and to the health care system in general can be contained by the rational adoption and use of medical technologies, which includes using them in appropriate settings. An important method of stimulating the rational adoption and use of technology is to foster competitive behavior by health care providers. In most cases, it is through policies encouraging the use of the alternative sites and organizations for health care delivery that competitive behavior is expected to occur.

This chapter presents an overview of some of the most prominent mechanisms to increase competitive behavior by providers. Alternatives to traditional fee-for-service, solo physician office practices and traditional inpatient hospital care include site alternatives such as freestanding ambulatory surgery centers, emergency care centers, hospices, hospital outpatient departments, home health care, and nursing homes. They also include organizational alternatives such as health maintenance organizations (HMOs), the use of primary care gatekeepers, and preferred provider organizations (PPOs). Organizational and site alternatives are not precisely distinct entities, but they are separated here for the purpose of discussion. This chapter defines several alternatives, discusses available evidence on their cost and quality of care, and discusses Medicare's past experience or possible future involvement with them. The chapter does not provide an exhaustive list of alternatives. More descriptive information on the selected alternatives is presented in appendix D.

Alternatives to traditional modes and sites of care have been initiated and developed in response to a variety of factors. In many instances, such as the development of freestanding ambulatory surgery centers and HMOs, factors for change have included technological advances, perceived patient need, and potential financial reward for the entrepreneurs. Changes in the health care delivery system have been influenced by, and had an effect on, the development and use of technologies. As noted in chapter 2, some changes in technology and in the health care delivery system have also been influenced by Medicare. It is the optimal blend of Medicare's adoption of pre-established health care system innovations and of Medicare's fostering innovations with which much of the discussion in this chapter is concerned.

Changes in the structure of the Medicare program itself are also examined in this chapter. These changes (vouchers, in particular) overlap with mechanisms to increase competition among providers but are presented separately for ease of discussion.

MECHANISMS TO FOSTER COMPETITIVE BEHAVIOR BY PROVIDERS

In an October 1982 report (355), OTA noted that strategies to increase competition in health care generally fall into three major categories: 1) increased cost-sharing by patients when they use medical care; 2) greater competition among comprehensive care organizations (i.e., organizations that provide health insurance and deliver medical care); and 3) increased antitrust activities by the Federal Government. The first strategy, increasing cost-sharing when patients use medical care, relies on the cost consciousness of patients to deter their initiation of care and to temper their own use of technologies as well as use generated by providers (355). Beneficiary cost-sharing proposals were discussed in chapters 6 and 7. The focus here is on the development of alternatives to traditional organizations and sites of health care delivery. Antitrust activities are excluded, because they are beyond the scope of this report.

Proponents of greater competition in health care believe that the changes they propose have the best chance of moderating medical care use and costs in the near future. Proponents of competition among health care plans emphasize the importance of creating incentives for providers to perform efficiently. They point to the largely untapped potential to use medical technologies more judiciously and to hospitalize less frequently, and would rely on alternative delivery systems to rationalize technology use and to achieve lower medical expenditures (355).

Under competition theory, providers' behavior is expected to change as patients become more conscious of cost in deciding whether or not to use services and shop for services on the basis of cost and quality. Physicians are expected to continue to guide patients as they do under traditional fee-for-service payment incentives, but their advice is expected to reflect to a greater extent concerns about the effect on their patients' finances. And hospital administrators are expected to become more conscious of costs in the management of their institutions (116).

Because "the sick or worried patient is in a poor position to make an economic analysis of treatment alternatives" (102), some proponents of competition conclude that the appropriate point for a rational economic choice is the annual selection of a health insurance plan. Attempts to increase competition among comprehensive care organizations, therefore, would place the critical choices by consumers at the point of insurance coverage rather than at the point of use of services.

Physicians strongly influence the adoption and use of medical technologies. For example, they may purchase sophisticated diagnostic equipment for their office use, or they may persuade hospital administrators and boards of trustees to purchase it. In their decisions, hospital administrators or boards may consider the importance of individual physicians in admitting patients and the various specialties competing for the technologies, as well as the cost of the new equipment and its benefits to patients. They may also consider the extent to which the physicians use the technologies already available.

To increase competitive behavior by providers, Medicare could be used to encourage further development of alternative delivery methods. Alternatively, Medicare could be restructured to embrace alternative methods of delivery (instead of providing exceptions for demonstration and evaluation of alternative methods), with the expectation that the health system already has the capacity to provide the preferred modes of delivery. Conclusions as to which is the preferred approach will depend on the answers to two closely related questions: 1) what is Medicare's leverage in promoting or requiring that alternative delivery methods be substantially available? and 2) what is the capacity of the health care system to provide these alternatives? Their answers will affect both the substance and pace of change in moving Medicare to a competitive system of insurance.

Alternative Sites of Health Care Delivery

Patients can obtain different types of medical care in a variety of locations. Examples of alternatives to inpatient hospital settings are ambulatory surgery centers, home health care, nursing homes, and hospices. Examples of alternatives to physicians' offices for the delivery of primary care are hospital outpatient centers and emergency care centers. Each of these alternative sites is discussed further below.

Ambulatory Surgery Centers

Units to accommodate ambulatory surgery were developed in the early 1970's in response to overcrowded operating room schedules and inconvenience to patients and physicians (125). These units could not have been established without the technological improvement of fast-acting anesthesia and the development of the practice of encouraging patients to walk soon after surgery (125). Some of the units are affiliated with hospitals and are located either in the hospitals or at other sites. Others are not associated with hospitals and are known as freestanding ambulatory surgery centers. The latter are often physician-owned. Surgical procedures that are appropriate to these centers are procedures using general anesthesia but requiring only a few hours of postoperative monitoring of the patient. Patients are carefully screened. In recent years, third-party payers have accepted claims for surgery performed in these centers, and some now require that certain procedures be done on an ambulatory basis for coverage.

In 1982, Medicare began to pay 100 percent of a fixed fee for the facility and a surgeon's fee (if the physician accepts assignment) for 100 specific surgical procedures if they were performed in freestanding ambulatory surgery centers (108). Historically, Medicare had paid 100 percent of costs (after the deductible and copayments) for inpatient, hospital-based tests and procedures including surgery through Part A but only 80 percent of an allowable charge for outpatient technologies through Part B. The 1982 change represented an overt attempt by Congress to encourage Medicare patients and their physicians to use the less costly ambulatory surgery centers when the quality of care they provided was at least as good as, if not better than, that provided in a hospital inpatient setting. The effect the Medicare coverage change has had on the use of inpatient or ambulatory surgery in the first year is thought to be minimal (177).

Medicare's prospective hospital payment system based on Diagnosis Related Groups (DRGs) provides conflicting incentives for the use of ambulatory surgery. On the one hand, the first criterion for categorizing patients into DRGs is the presence or absence of a surgical procedure, and the strongest financial incentive of DRG payment is to increase hospital admissions. On the other hand, hospitals may try to shift some of their patient care to their own outpatient departments, including ambulatory surgery departments, where the DRG system is not in effect.

Home Health Care

Another care setting to which Medicare patients may be discharged from hospitals is their homes, where home health agencies can provide care. The specific aspects of home health care have changed over time. Currently, the basic services include part-time or intermittent nursing care by or under the supervision of a registered nurse; physical, occupational, or speech therapy; medical social services; and part-time or intermittent services from a home health aide. Certain medical technologies (e.g., intravenous antibiotic therapy) that used to be administered only on an inpatient basis are now part of home health care (248). Home health services are usually provided by independent public or private home health agencies but can also be provided as an outreach service by hospitals.

Continued growth in the home health industry is expected in response to the financial incentives for shorter hospital stays provided by the DRG payment system. The number of agencies providing home health care services has greatly increased since 1966 when Medicare began covering skilled nursing care and physical and speech therapy to homebound elderly people (207). The purposes of providing those services was to lower the hospital length of stay for acutely ill patients, thus cutting costs to the program.

Studies of home health care in the 1970's seemed to indicate that home care made early discharges from hospitals possible. Recent studies have examined overall nursing home and hospital use and found no reductions in length of hospital stay, although patient satisfaction and life expectancy were improved. These studies did not address readmission rates or length of stay (333). Thus, the long-term effect of the early discharges on the substitution of home care for hospital care is not evident.

Nursing Homes

The Health Care Financing Administration (HCFA) has categorized nursing homes as either skilled nursing facilities (SNFs) or intermediate care facilities (ICFs). More types of medical technologies for treating inpatients and more intensive levels of care are available in an SNF than in ICFs. Medicare covers 100 days of care in an SNF following an acute episode of illness, but it does not cover care in ICFs.

Not all SNFs accept Medicare patients and payment. This is partly because of some financial risk posed by the possibility that Medicare intermediaries (contractors who administer Part A) may deny payment and partly because Medicare patients may require more intensive nursing care and more use of medical technologies than other SNF patients (106). There are shortages of SNF beds for Medicare patients in parts of the country (106).

As an alternative to inpatient hospital care, care in SNFs is less costly. The intensity of care differs between hospitals and SNFs, so their patient populations also differ. SNF patients have usually spent time in a hospital before being admitted to a nursing home. Under the old cost-based hospital reimbursement system, Medicare paid as much as four times the necessary cost of care for patients waiting in hospitals for SNF beds (106). Under the DRG payment system, if a patient remains in the hospital because SNF-level care is unavailable, the days are counted just like other inpatient days. If the length of stay exceeds the DRG average by a specified amount, Medicare will pay the hospitals a per diem outlier rate. In part because DRG payment provides incentives for hospitals to discharge patients to SNFs, Medicare costs for SNF-level patients in hospitals may decrease. Discharges of sicker patients to SNFs could affect the need for more technologies in the SNFs. It could also increase Medicare's costs for SNFs, which may offset the Medicare hospital savings.

Hospices

Hospice care has been available to terminally ill patients in this country since 1971. Treatment consists of palliation of the patient's symptoms and psychosocial care from a multidisciplinary team of physicians, nurses, social workers, clergy, psychiatrists and psychologists, dieticians, lawyers, and specially trained volunteers. By allowing most patients to remain in their homes rather than the hospital, hospice care saves costs. It also is more pleasant for the patients.

Hospice care is a recently enacted Medicare benefit. Legislation to cover hospice care was passed in 1982, while the National Hospice Study, which was to assess the costs and quality of care in a national sample of existing hospices, was still in process. At the time of the benefit addition, preliminary results seemed to show that hospice care would be cost effective for Medicare. The incentives for hospitals to encourage their patients to use their hospice benefits depend on whether the hospital runs its own hospice and on whether the patient might be an outlier case for whom the hospital might be paid some additional, marginal costs. The effects of the new benefit for hospice care on the quality of life for terminally ill patients are unknown. Also unknown are the costs of the benefit to Medicare and to the beneficiaries. Technology use in hospice care, whether home or hospital based, was significantly lower than use in conventional treatment of terminal cancer patients in the National Hospice Study, while quality of life seemed to be about the same in the different sites (146).

Hospital Outpatient Departments

Outpatient departments of hospitals may be an alternative site to both inpatient hospital care and private physician office-based care. Many hospitals, particularly teaching hospitals, have long had outpatient services, including primary care. Furthermore, in recent years, one of the ways hospitals have responded to financial pressures has been to expand hospital services, including primary care in outpatient departments (136). Other reasons for the increased use of hospital ambulatory care are low access to private physicians, particularly for some inner-city residents (2), increasing prevalence of chronic diseases (2), greater patient expectations regarding hospitals (2), and advances in medical technology that have allowed movement from inpatient to outpatient settings (136,157,248).

Under Medicare's current payment system, hospital outpatient departments receive payments through Part B, based on the hospital's costs. Because hospital overhead costs are high, Medicare payments for outpatient department visits are usually higher than physician office charges. However, unlike physicians, hospitals must accept assignment to participate in Medicare, so Medicare beneficiaries' costs for outpatient visits may be lower than those for physician office visits. Costs to Medicare are generally higher for outpatient department care than for office care. There is evidence that increasing numbers of patients 65 and older are using outpatient visits for primary care (210).

Emergency Care Centers

Emergency care centers are alternatives to hospital outpatient departments, to some emergency room care, and to primary care in physician offices. Such centers are generally equipped with some emergency technologies but do not treat life- or limb-threatening situations, so the name "emergency" may be misleading (325). They usually have more diagnostic technologies on location than a physician's office. Emergency care specialists and some family practitioners have opened emergency care centers to make medical care more accessible to patients who have no primary care physician or who cannot find a physician after hours. The centers have extended hours during evenings and weekends when physicians' offices are closed, and some are open 24 hours a day, 7 days a week. No appointments are necessary, so care is more convenient for some patients, although patients may not experience desired continuity of care.

Emergency care centers usually compare their charges with those of hospital emergency rooms rather than with fees for physician office visits. This comparison is not necessarily a good one, because the care provided is often more like office than hospital care. Nonetheless, the National Association of Freestanding Emergency Centers estimates that center charges are 30 to 50 percent lower than hospital emergency rooms for comparable services (238).

If an emergency care center is hospital-affiliated, Medicare will reimburse for visits as though the center were a hospital department. If the center is totally independent, Medicare will pay as though the visit were a physician office visit (55). As noted earlier, hospitals must accept assignment to participate in Medicare, but physicians need not. Thus, if elderly patients were informed about which centers were hospital-affiliated (and thus accepted assignment), they would be more likely to choose them over the independent ones if total prices were comparable. A 1979 study showed that most of the emergency care centers' revenues came from private insurers or patients who paid directly, with only a small fraction coming from Medicaid and even less from Medicare beneficiaries (55). The 1983 followup, although limited in sample size, showed more centers accepting Medicare funds but some centers specifically excluding Medicare cases (248).

Alternative Organizations for Health Care Delivery

Organizational differences among providers allow patients choices and increase competition in the health care market. Two examples of alternatives are described below, HMOs and PPOs. Also, primary care gatekeepers are discussed.

Health Maintenance Organizations

An HMO is a defined set of physicians and other health care providers who provide services for a voluntarily enrolled population that pays a prospective per capita amount. HMOs provide both insurance benefits and comprehensive but specified medical care, and are often cited as the cost-effective mode on which competitive care could be built.

In a series of laws, the Federal Government has encouraged the development of HMOs in the belief that health care costs will be contained by this organizational type. Even with the special governmental treatment, however, HMOs cover only about 5 percent of the U.S. population (392). HMOs cover an even smaller proportion of Medicare beneficiaries: approximately 2 percent of the Medicare population is enrolled in an HMO-like organization (392). The evidence on why so few Medicare beneficiaries are HMO members is inconclusive, but some possible reasons include a lack of interest in or knowledge about HMOs on the part of the Medicare population and a lack of interest in enrolling an older, sicker group of people on the part of HMOs. Another reason may be that beneficiaries need incentives to join HMOs, because they would probably have to change physicians and hospitals. Finally, another consideration is that HMOs operate on a per capita payment basis, and as long as Medicare required cost-based data, the HMOs incurred significant administrative costs.

The cost effectiveness of HMOs has been thoroughly studied. The empirical evidence on costs and quality of care for HMOs verifies the predicted behavior: patients *are not* constrained from seeking necessary care, and, at the same time, physicians *are* constrained from using unnecessary medical technologies, including tests, procedures, and hospitalizations (206). HMO physicians are usually salaried, and because they often share in the HMO's surplus revenues, they have financial reasons to keep general costs and, specifically, the number of office visits low. HMOs provide incentives to providers to use fewer laboratory and radiological tests on an ambulatory basis. HMO physicians hospitalize patients less frequently than non-HMO physicians (204). Office visits that have doubtful cost effectiveness, such as annual physical examinations for healthy individuals, might be discouraged by HMO physicians, but in many cases, patients initiate such visits themselves. Studies have shown that although HMOs use fewer medical technologies, they do provide care that is at least as good quality as fee-for-service care, and their costs are lower (204,206,429).

Primary Care Gatekeepers

One of the methods HMOs use to save costs is to have each patient choose a primary care provider who acts as a gatekeeper to specialists and other types of care (316). These primary care gatekeepers not only have the responsibility for referring patients to others, but they also coordinate all facets of a patient's medical care. The gatekeeper's coordinator role is especially important for elderly patients, who often have multiple diseases and must take a variety of drugs that may interact dangerously.

The gatekeeper is neither a new concept nor confined to a particular payment method (316). The "traditional" family physician who took care of most medical problems and referred patients to specialists when necessary was an informal gatekeeper. Several years ago, the SAFECO Insurance Co. experimented with a primary care network in Seattle that used physicians as gatekeepers. The experiment showed that the gatekeepers must have financial risks for referring too many patients to specialists, or there are no cost savings to the insurers (277). Great Britain's National Health Service uses general practitioners as gatekeepers. Their effectiveness is questionable, however, because there is a growing private medical care sector for people who do not want to wait for specialists' care and can afford to pay for it privately.

The evidence on technology use by physicians as gatekeepers comes from the literature on HMOs and Great Britain's National Health Service. Physicians in HMOs hospitalize patients less often and use fewer medical technologies in their roles as gatekeepers (204). Evidence of constraints on technology use in Great Britain include long waiting periods for elective surgery and an age cutoff for new hemodialysis patients (316). The evidence from Great Britain must be viewed with caution, because there are substantial differences between the health system of Great Britain and that of the United States.

Clearly, the gatekeeper performs a rationing function. How this rationing of health care services would be interpreted in light of the freedom of choice enjoyed by Americans in the health care system is unknown. Could the concept be introduced in the Medicare program, thereby limiting choice for elderly and disabled patients only? A demonstration project of case management (i.e., gatekeeper) for Medicaid patients in Massachusetts was ready for implementation but was canceled by the new governor for political reasons. Patient groups could be appropriate targets for experiments with gatekeeper approaches, but such special treatment might result in two-class medicine.

Preferred Provider Organizations

PPOs are new entities that are designated to combine some of the features of HMOs with those of fee-for-service medicine. A PPO is an agreement among providers (usually hospitals and physicians), patients, and insurers that medical care will be delivered at a discounted price as long as the patients use the "preferred providers" (i.e., providers who are among the contractors). Discounted prices and utilization review agreements should result in the use of fewer medical technologies by PPOs. Since payment is on a fee-for-service basis in PPOs, however, providers' financial incentives to use more ancillary services may be as great as in the traditional mode of care. The effect of PPOs on the use of medical technology will depend in part on the effectiveness of the organizations' utilization review programs. The PPO concept is relatively new, and there are no reliable data on which to base predictions about how PPOs will interact with Medicare or the overall health care delivery system. Currently, Blue Cross and Blue Shield of Michigan is developing a PPO for Medicare recipients in Detroit under a grant from HCFA (59).

ADMINISTRATIVE CHANGES IN MEDICARE

The alternatives addressed in this section focus on Medicare's structure. There are definite overlaps between the administrative changes discussed here and the competitive mechanisms presented above. Vouchers, for example, would encourage competition among providers *and* change Medicare's makeup. The separation is to facilitate discussion.

Merging Parts A and B

It is well known that separate income and payment mechanisms for Parts A and B of Medicare have led to inefficiencies. Some medical technologies have been covered under both Parts A and B, but because of differences in which part paid for their use at which time, there has been unnecessary duplication of equipment in adjacent facilities. This effect could be avoided if there were one type of coverage and one payment source. Thus, merging Part A and Part B would thwart efforts to shift costs from one part to the other and should decrease the supply of some of the excess technologies. The incentives to open a new freestanding facility for diagnostic tests across the street from a hospital equipped to do those tests would be reduced by the elimination of the cost-shifting possibility.

There is no sound fiscal reason for separating Part A—the Hospital Insurance (HI) program—from Part B—the Supplementary Medical Insurance (SMI) program—which covers physician services. There is also no sound health reason for the separation. Merging the two parts could alleviate the financial problems of the Medicare program and improve quality of care for patients.

Davis and Rowland (84) have proposed that a comprehensive, integrated set of benefits be substituted for those under Parts A and B and be paid from a single trust fund formed from the HI and SMI funds. Everyone eligible for Part A would be covered; no benefits would be optional. According to Davis and Rowland, their suggestions for Medicare revenues would guarantee the future solvency of the Medicare program and the availability of medical care for its beneficiaries. Revenues would come from: 1) the current payroll tax contributions to the HI trust fund; 2) general revenues currently projected for SMI expenditures; and 3) new beneficiary premiums that would be related to income and administered through the personal income tax system. The proposal assumes that cost-containment efforts and incentives for providers to improve efficiency would continue.

The merger proposed by Davis and Rowland focuses on financial solvency through revenue reforms for Medicare, but such a merger would also provide incentives for new organizational innovations fostering competitive behavior among providers. Medical technology adoption and use would be more directly affected by the efforts following the merger to increase provider efficiency than by the actual merger described. It might be possible, for example, to initiate a gatekeeper approach that would penalize the primary physician for inappropriate hospital admissions, thus putting the onus on the decisionmaker. The merged Medicare program would be better able to administer such a system than the current separate data systems.

Vouchers

Vouchers are seen by some policymakers and analysts as an important alternative to change Medicare and contain costs. A voucher system would allow each eligible person a set amount of money with which to purchase medical care and/or health insurance. In some voucher systems, people who did not spend their entire amount would be able to keep the remainder. Under most systems, though, more benefits would be added to basic coverage to spend up to or over the voucher amount. Any costs of insurance benefits over the voucher amount would be paid by the patient.

Medicare vouchers have been proposed in Congress several times as a capitation payment method. A Medicare voucher system is attractive for a number of reasons. First, a fixed-dollar subsidy is a capitation method of payment, which would make it easier for HCFA to predetermine and control the program's expenditures. Second, a voucher system could substitute for or complement the service-by-service (e.g., ambulatory surgical centers, hospices) and provider-by-provider (e.g., HMOs, PPOs) revisions in current Medicare policy that attempt to fine tune the program in its search for cost-effective alternatives to traditional methods of delivering medical services. Third, such a system would provide Medicare enrollees with a greater choice of insurance plans, in contrast to the present single Medicare program with its increasing amount of cost-sharing and perhaps decreasing access to physicians of the enrollee's choice. And fourth, Medicare's enrollees' ability to enter the general marketplace for medical services could lead to significant competition for their care and accelerate the development of cost-effective methods of providing medical care.

The entry of Medicare enrollees into the medical marketplace through a voucher system raises three questions. First, will a voucher system generate cost savings to Medicare? Second, at what pace and to what extent should the Medicare program be integrated into general health insurance plans? And third, to what extent could Medicare patients adapt to such a new system?

The answers to the latter two questions are primarily philosophical. Cost savings to Medicare will depend on the voucher's initial value and future increases in value. Currently, Medicare pays for hospital and physician services at lower rates than the private sector does. If the value of the voucher is set at average per capita expenditures per Medicare enrollee, insurers that enroll Medicare beneficiaries may have to reduce benefits or raise premiums to cover their actual costs. Insurers also incur costs that Medicare does not, such as advertising, reserve requirements, premium taxes, as well as profits, all of which would have to be built into the premiums.

Voucher proposals link future increases in the voucher's value to indexes that have increased at lesser rates than medical costs, such as the Consumer Price Index. If medical costs continue to increase at a faster rate, premiums would have to be raised above the voucher's value or benefits would have to be curtailed (336). Thus, in order for Medicare enrollees to have the same level of benefits as under the current Medicare insurance program, initial expenditures would have to increase, and if medical costs continue to outpace general inflation, future costs would be comparable to increases in costs under the present program. If the initial value of vouchers is kept at the level of current expenditures, and if future values increase less than medical costs increase, average benefits would be less or the voucher would not be sufficient to cover premiums for most beneficiaries.

Most legislative proposals to date would allow voluntary participation in a voucher system, although some of the proposals would allow beneficiaries to reenroll in Medicare and others would make the decision to participate permanent. A voluntary system could initially increase per capita Medicare costs if low-cost users selected private plans while high-cost users chose the traditional Medicare option. If benefits for the low-cost users decreased in their plans, they would choose to go back to Medicare's regular benefits. One of the alternatives is a mandatory voucher system if and when more than half of the beneficiaries choose vouchers (336). Under a mandatory voucher system, which would replace the present Medicare program and in which Medicare beneficiaries would be required to purchase insurance from the marketplace, Medicare program expenditures could be kept the same as current expenditures. Beneficiaries, however, might have to pay more premiums or have their benefits reduced. None of the legislative proposals to date have included mandatory vouchers, though the conditions vary.

Voucher problems for both insurance companies and Medicare beneficiaries deserve consideration. Individual policies would have high administrative costs, and many insurers have indicated they would not sell to the Medicare market (156). Many of Medicare's elderly and disabled beneficiaries may not understand the differences in insurance policies and may be excluded or disadvantaged by policy exclusions and preexisting condition costs. Furthermore, beneficiaries' mobility problems may hamper comparison shopping for the best deal.

Technology incentives would depend on the method of payment from the insurance companies to the physicians. If physicians accepted capitation payments for Medicare patients, they would have financial incentives to use the fewest possible and least costly medical technologies while still providing good quality care. If they continued to be paid on a fee-for-service basis, their financial incentives would remain much as they are now. It is unlikely that insurance companies would choose the latter path.

The choice between mandatory and voluntary voucher systems raises several issues. A voluntary voucher system would present Medicare beneficiaries with the choice of joining other insurance plans on a test basis to see if there would be more cost-effective services available to them than under the present Medicare system. A mandatory voucher system would take advantage of the market power of Medicare enrollees as incentives for providers to develop more cost-effective approaches, but would place beneficiaries at greater risk for increased cost-sharing and reduced benefits if providers failed or were slow to respond. A voucher system might also weaken the influence of Medicare as a large payer for hospital cost control.

DISCUSSION

Medicare has fostered certain patterns of care because of its payment policies and program structure. The program has influenced how much and where specific medical technologies are provided. For the most part, Medicare has fostered inpatient hospital care and adoption and use of technologies. The End-Stage Renal Disease (ESRD) program (see ch. 2) also illustrates the influence of Medicare with the growth of the dialysis center industry. It is doubtful whether, without Medicare coverage, the market would have stimulated the research and development for some ESRD technologies such as continuous ambulatory peritoneal dialysis. Provided that the alternative sites and modes of care are truly believed to have a beneficial impact on costs and on technology adoption and use, can Medicare stimulate their development?

The Medicare program has not been used to its full extent to encourage or discourage alternative sites and organizations of care, in part because of the original political agreement that the Federal Government would not use Medicare and Medicaid to interfere in the practice of medicine. Despite the noninterference policy, however, Medicare was certainly intended to influence, and in fact has influenced, the practice of medicine through the conditions of participation and other quality of care standards provided by the Professional Standards Review Organizations (see ch. 7). The key is that Medicare has influenced medicine in a politically acceptable manner, because it has traditionally included the medical profession in its decisions. The separation of Medicare payment for inpatient hospital care (Part A) and for physicians and other types of care (Part B) has had an effect, though not purposeful, on the changes in medicine.

As a large single buyer of hospital inpatient care, Medicare has always had a significant impact on the availability and use of hospital-based technology. The DRG hospital payment system is explicitly designed to provide incentives for more efficient provision of care, and because of Medicare's size, changes in hospital behavior are predicted to be realized. The actual effects of DRG payment on the adoption and use of medical technologies by the hospital industry and alternative sites and organizations of care will provide policymakers with necessary information for future change.

Medicare's leverage for initiating changes in alternative sites or organizations of care is not as great as it is for initiating changes in hospitals. If Medicare used its purchasing power prudently, competition and alternative delivery systems could be either fostered or hindered. It would probably be more appropriate for Medicare policies to be neutral for sites and organizations of care until the evidence on cost effectiveness is more conclusive. For example, the removal of freedom of choice of providers from one segment of the population by requiring case management of Medicare patients may raise ethical questions. Would a voucher system increase freedom of choice of benefits, and would the insurance industry participate in such a program? Whether it is reasonable to expect Medicare to pay for the most expensive, optimal level of health care or to pay less for an adequate level of care is also at issue. If Medicare chooses the latter route, a possible result would be a system of two-class medicine.

More targeted Medicare program changes to stimulate the use of alternative cost-effective modes of care may add to Medicare's costs in the short run, until these alternative modes are more firmly established in the health care system. HCFA's efforts to stimulate the use of cost-effective modes of care are reflected in recent changes in the ESRD program (see ch. 2) and in Medicare demonstrations on risk-contracting for HMOs (see app. D).

In the ESRD program, the imposition of composite reimbursement rates to stimulate home dialysis care makes Medicare payment rates for home dialysis higher than the actual costs. Home dialysis costs may rise because of the need for home health aides for patients with little family support. If costs do not rise significantly and the use of home dialysis does increase greatly, Medicare will be paying at a rate much above costs. Whether there will be a savings to the ESRD program with the redistribution of dialysis patients between home and center dialysis is not clear. Also not clear is whether the large difference between costs and payment levels (estimated at nearly 50 percent (344) will continue to be justified.

HCFA's HMO risk-contracting demonstration programs involve the same issue—paying more initially to establish alternative sites or modes of care, yet leaving unresolved for future consideration how these alternative modalities can be sustained at payment levels lower than originally needed to stimulate their participation in Medicare. Payments in HCFA's risk-contract demonstrations were set at 95 percent of average adjusted per capita costs of providing fee-for-service care to these enrollees in the HMO's service area. Thus, payments in these demonstrations were set above the HMO's cost levels, with the extra payment to be used to induce Medicare beneficiaries to enroll through extra benefits or decreased premiums (97). Again, left for future consideration is the payment level to HMOs if and when they gain a significant share of the medical market for Medicare enrollees.

If the DRG payment system continues to be the only change in Medicare, what effects are predicted for the rest of the system? Care in SNFs, ICFs, hospices, and in the home will probably increase in response to the financial incentives to shorten hospital lengths of stay. In some cases, therefore, sicker patients will be treated in these alternative sites. To the extent that the alternative sites have the facilities and staff to give appropriate care, such treatment might not lower the quality of care. If the patients are so much sicker that their treatment in alternative sites necessitates the hiring of new staff or the purchase and use of new technologies, however, the cost of care in the alternative sites will increase. In addition, the current DRG prices reflect average lengths of stay in hospitals. If patients move to other sites for the final convalescent days of care and the DRG prices do not reflect the change, Medicare would essentially be charged twice for the convalescent care.

Policymakers concerned with the Medicare program have shifted their emphasis from making mainstream medical care available to the elderly and disabled to a search for more cost-effective methods of providing care. Detailed, specific changes have been made, which still preserve the basic framework of the Medicare insurance program and its separate hospital and physician reimbursement parts. The development of alternative modes of care, and step-by-step revisions in the original Medicare legislation in order to adopt and nurture these alternatives, are gradually transforming Medicare away from a cost- and charge-based retrospective system of payment. The direction of these changes is clearly toward a total, prospectively determined system of payment and toward providers with both financial and service responsibilities.

The transition to cost-effective modes of care raises issues that can only be resolved with experience. At least for the short run, alternative methods of care may add to costs—as when home health care supplements instead of replaces hospital and nursing home care—or they may require payment levels similar to the fee-for-service system to build up their presence—as in the case of HMOs serving the elderly. In the case of vouchers, cost-containment objectives have to be balanced against the use of Medicare enrollees to test economic theory in practice and the probability that at least some of the Medicare program's cost savings will come at the expense of increased cost-sharing and/or reduced benefits for Medicare enrollees.

Medicare's leverage in the health care system is variable and depends on which segment of the system is examined. If the Medicare program is to be changed, is it sufficient for Medicare to try reforms, or must the alternatives exist in the system so that Medicare can incorporate them? Alternative sites and organizations for health care delivery are currently available for experiments or revisions in the Medicare program. The extent to which these alternatives could adapt quickly and adequately to a major change in Medicare policy is being tested by DRG hospital payment.

Clearly, Medicare policies can provide small steps, as they have by the special coverage for ambulatory surgery in freestanding centers and for hospice care. Parallel developments of alternatives in the health care system outside of Medicare will continue. Policymakers should watch these system developments and modify Medicare policy to take advantage of new cost-effective modes or sites of care when available. Finally, the decision must be made for the Medicare program either to keep and strengthen its purchasing power by continuing to cover beneficiaries in a large program or distribute its beneficiaries into the marketplace by means of a voucher system. Either of these actions has implications for technology innovation and diffusion and for cost control.

Part Three

9.

Findings and Policy Options

> Nobody can really guarantee the future. The best we can do is size up the chances, calculate the risks involved, estimate our ability to deal with them, and then make our plans with confidence.
>
> —*Henry Ford II*

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9.
Findings and Policy Options

INTRODUCTION

The dual relationship between medical technology and the Medicare program has been explored in previous chapters: Medicare policies affect the adoption and use of medical technologies, and patterns of use of medical technologies significantly affect the types and levels of Medicare costs. This chapter identifies several options for changes in Medicare policy that could be used to influence medical technology adoption and use and to restrain Medicare program costs.

Medicare policy can influence the adoption and use of medical technologies in order to cut program costs both through policies directed specifically toward individual technologies and through policies that provide broad incentives for rational adoption and appropriate use of medical technologies. This chapter presents findings and policy options by issue area within each of these two broad policy areas. The first section of this chapter focuses on policies directed at individual technologies and contains options pertaining to Medicare coverage policy. The second section focuses on policies that provide broader incentives toward technology and contains options directly concerning Medicare hospital and physician payment and approaches encompassing interactions between Parts A and B of Medicare as well as interactions between Medicare and the general health care system.

The options identified in this chapter generally fall into the following categories:

- changes in Medicare's coverage policy for specific technologies;
- changes in the methods of Medicare payment to hospitals;
- changes in the methods of Medicare payment to physicians; and
- approaches to changing the incentives for the adoption and use of technology that do not directly involve, but may be related to, Medicare payment mechanisms (e.g., encouraging the development of alternative cost-effective health care delivery systems).

Some of the options involve direct legislative action. Others are oriented to the actions of the executive branch but would involve congressional oversight or encouragement.

The order in which the options are presented is not meant to imply priorities among them. Furthermore, the options are not, for the most part, mutually exclusive. Adopting one option in any category does not necessarily imply that others are inapplicable within that category or within any other category. More often, a careful combination of options can better produce the intended effects. In some cases, an option may suggest improvements for more than one aspect of Medicare policy. It is important to keep in mind that changes made in one area have repercussions in other areas.

COVERAGE OF SPECIFIC MEDICAL TECHNOLOGIES

ISSUE:

How can Medicare's coverage process for specific technologies be improved?

It is generally agreed that third-party coverage policy has influenced decisions about the purchase of some expensive, visible medical technologies. Thus, the coverage of specific technologies is a potential method of containing Medicare costs through control of the diffusion (i.e., adoption and use) of medical technologies. In the present cost-conscious environment, the attention of policymakers may become focused on expensive technologies, i.e., both technologies with a high capital purchase price and technologies with lower capital purchase prices but high utilization. Long-term effects of other technologies, however, should be considered in Medicare coverage decisions. The precise relationship between coverage policy and purchase of other kinds of medical technologies or the use of any technologies remains speculative.

The benefits for which Medicare will pay are designated in broad general categories such as inpatient services, outpatient services, and physicians' services. With few exceptions, therefore, Medicare coverage policy is determined at the local or national level on a technology-by-technology basis. Coverage decisions by Medicare contractors or by the Health Care Financing Administration (HCFA) follow the statutory mandate which excluded Medicare payment for items and services that are not "reasonable and necessary" for diagnosis, treatment, or improved functioning of a malformed body member. "Reasonable and necessary" items and services are interpreted as those that meet four criteria: general acceptance as safe and effective; not experimental; medically necessary; and provided according to accepted standards of medical practice in an appropriate setting. **Evaluation of the nonmedical effects, for example, economic and social effects, of a technology is usually not part of a technology assessment for coverage purposes.**

HCFA officials and individual Medicare contractors have had considerable latitude in determining which technologies are to be covered for reimbursement. Furthermore, there is considerable variation in the implementation of national coverage decisions by Medicare contractors.

Uniform implementation of HCFA's coverage decisions might foster equal treatment of Medicare beneficiaries throughout the country.[1] However, although traditional local variations in the practice of medicine do mean that Medicare beneficiaries effectively receive somewhat different benefit packages, there is no evidence that local differences in standards of care affect patients' health. Uniform implementation of coverage decisions may discourage local differences, and some observers believe that it may interfere in the practice of medicine. The strength of such interference would depend on the influence coverage policy has on the adoption and use of medical technology in the first place.

The lack of necessary information on which to base assessments and coverage decisions is a serious problem. Although the guidelines used by the Office of Health Technology Assessment (OHTA) to evaluate the safety and efficacy of medical technologies stress the value of basing coverage recommendations to HCFA on data from controlled clinical trials or other well-designed clinical studies, in many cases, such data are unavailable.

Furthermore, **timeliness of identification of new or outmoded technologies is important to Medicare, because the assessment process is itself time-consuming.** Some technologies, such as heart transplantation, are so expensive and visible that they have been identified, but a coverage decision has been delayed. In the case of the artificial heart, the ostensible reason for the delay is to allow a thorough assessment of the technology's safety, efficacy, and other aspects. Some analysts have noted that the true reason behind the delay is cost containment (22,258). Such delays in coverage decisions may save Medicare program costs for a time. Sometimes the coverage decisions are slowed by the backlog of technology assessments faced by OHTA. In other cases, new techniques, such as coronary artery bypass graft (CABG), have been paid for by Medicare under existing procedure codes. By the time payment issues were raised, CABG was considered generally accepted medical practice.

A new issue for the Medicare program is the role of coverage policy with respect to the new Diagnosis Related Group (DRG) prospective payment system for hospitals. Although the coverage process and the DRG-rate adjustment process share a similar "approval for payment" function, they differ in that a coverage determination focuses on a specific technology, while adjusting DRG payment rates focuses on the larger entity of a diagnostic group, which includes particular technologies. Moreover, the DRG-rate adjustment process must include issues of cost as an integral issue, while the coverage process at present does not consider cost issues. **Despite their differences, the technology assessments performed for the coverage and DRG rate adjustment processes no doubt will have similarities, and their coordination should be encouraged.**

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[1] It should be noted, however, that current national coverage policy is considered an interpretive rule and does not have the force of law.

An idea related to the coverage process that may be worth exploring is the use of Medicare conditions of participation[2] to influence the adoption and use of individual medical technologies. A new condition of participation for hospitals, for example, could require that hospitals have technology assessment committees. The *process* of explicitly discussing safety, efficacy, and cost questions before a hospital purchases, and physicians use, a particular technology may be worthwhile. A major finding of OTA's 1980 assessment of cost-effectiveness analysis (CEA) in health care was that the *process* of identifying and considering costs and benefits in CEA might be more valuable in decisionmaking than the rigid and formal application of CEA results in health care program decisions (353).

There is no process of identifying and considering costs and benefits in CEA for a hospital that is yet acceptable to all concerned, however, nor is there evidence of effectiveness of such processes in making technology adoption or use more rational. In part, this is because **a decision that is rational from a hospital's perspective may not be rational from society's perspective.** Furthermore, Medicare conditions of participation are being simplified under the current Administration to reduce the burden of administering detailed nonstatutory requirements. Adding a new condition of participation would be counter to that objective. In addition, hospitals may decide to use technology assessment committees under the DRG payment system even without the requirement because of the complexity of the incentives. Many hospitals already have purchasing departments or committees that perform the function of assessment with variable rigor.

Option 1: Amend the Medicare law to allow coverage for emerging technologies on an interim basis in exchange for data on their safety, efficacy, and costs.

Implementing this option could improve the availability of data necessary for good coverage decisions and, ultimately, for the rational adoption and use of medical technologies.

Defining "emerging" technology is difficult. The movement of any technology from the research phases into common clinical practice represents a continuum, and there is no specific point at which a particular device or technique would stop being "experimental." Developing criteria would be necessary to ensure that interim coverage was not allowed too early in a technology's development in order to minimize the risks to patients involved in clinical trials.

Coverage of emerging technologies in return for data would yield new information on elderly patients—few previous clinical trials have collected data on such patients. Involving elderly patients in clinical trials would have positive and negative aspects. A disadvantage would be the inherent risks to patients involved in clinical trials of emerging technologies, although subjecting Medicare beneficiaries to technologies tested only on younger patients also involves risk. Designing clinical trials involving elderly patients is very difficult, because such patients usually have more than one medical condition.

Important decisions would have to be made. One such decision would be about how long to provide interim coverage. Time limits would have to be explicit from the beginning, if interim coverage were implemented. Another important decision would be where and to whom the interim coverage would apply. Sites and providers to conduct clinical trials would be selected as part of the research peer review process. Although the selection of specific sites and investigators for interim coverage might be regarded as favoritism, limiting Medicare coverage only to sites and investigators with very specific protocols would seem to be a more prudent approach than paying for the use of emerging technologies on a more widespread basis. Once an emerging technology's safety and efficacy had been established, coverage could be extended, or, if Option 2 were implemented, other appropriate sites and providers could be identified for permanent coverage.

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[2] Conditions of participation are requirements that must be met by providers in order to be allowed to receive payment for Medicare patients. An example is the requirement that hospitals conduct utilization review.

The collection of cost data is a key element of this option. Thus, this option is closely related to Option 3 below. If Medicare payment rates, particularly for Part B services, are ever to be based on technologies' costs instead of past charges, the Medicare program will need better cost data on which to set these rates. In the past, costs have often been unknown until technologies were already in widespread use.

Coverage of emerging technologies in exchange for data would initially add costs to the Medicare program, but the information gained could very well be worth the investment. The availability and interpretation of better data on the safety, efficacy, and especially costs of new technologies would provide a good mechanism for Medicare policymakers to decide how best to expand or contract benefits in a rational manner. Such coverage would shorten the usual delay involved in getting data from clinical trials on which to base coverage decisions. Although long delays may save Medicare costs in the short run, such delays may sometimes mean that some patients are denied efficacious technologies.

Option 2: Amend the Medicare law to limit coverage of complex technologies to their provision in selected sites by selected providers.

Certain medical technologies involve highly complex equipment and supplies and require a skilled team of providers. Limiting Medicare coverage for specified complex technologies to their provision in particular sites could help control Medicare costs and might also improve quality of care.

Theoretically, implementing this option would help control costs by reducing excess capacity. There would be a reduction in unused technologies in a number of sites along with economies of scale produced by having larger capacities at only a few sites. Certain surgical procedures performed in high-volume hospitals have better patient outcomes than the same procedures done in low-volume hospitals (124a). And for high volumes of complicated surgical procedures, the teams of surgeons, nurses, anesthesiologists, and medical technologists who work together would learn to work together more efficiently and effectively.

While limiting sites and providers could help control costs by limiting the adoption and use of complex technologies, it might also limit the numbers of patients who could be treated. If need exceeded capacity, a method for rationing care would be necessary.

Currently, private insurance companies cover exceptional technologies in selected sites: Blue Cross will pay for the heart-lung transplantation done at Stanford University. And Medicare itself has set some precedent by limiting payment for therapeutic apheresis to its use in specific settings and by specified providers (26).

A potential problem with selective coverage by Medicare is that such coverage could lead to two-class medicine. Nonselected hospitals, for example, could purchase major medical equipment that might not be covered by Medicare. Physicians in the hospitals might then use the equipment only for their non-Medicare patients. The probability of the occurrence of this situation would depend on the cost of the technologies and the availability of trained staff, as well as on the proportion of the hospital's patients who are Medicare beneficiaries.

The specification of providers and sites for certain technologies might be regarded as unequal treatment of providers. Yet in this option, as in the previous one, sites and providers could be selected on a peer reviewed basis to assure quality and to maintain acceptability within the medical profession. Peer review such as that undertaken by the National Institutes of Health (NIH) study groups would be one possibility.

The DRGs encompassing the specified technologies would have to be treated differently in selected hospitals (sites other than hospitals are not yet under the DRG payment system). Assuming that these complex technologies would be very expensive, Medicare hospital payment would somehow have to support their rational adoption and use (see Option 6). Otherwise, all cases using such technologies would be outliers.

Option 3: Mandate that Medicare coverage decisions include cost considerations when appropriate.

Because cost containment is so crucial in the Medicare program and in the health care system, it may be necessary to explicitly include cost considerations in coverage decisions. At present, the adoption and use of medical technologies involves *implicit* rationing of scarce dollars. In today's economically constrained environment, perhaps the tradeoffs among coverage decisions should be more explicit. Especially if Medicare covers high-cost technologies that yield few benefits, other services must be eliminated in order to decrease program expenditures.

Because Congress provided little guidance on how it intended the statutory "reasonable and necessary" tests to be applied, the question of the appropriateness of using cost information in Medicare coverage decisions has been raised by the U.S. Department of Health and Human Services (DHHS) several times. DHHS has asked its legal counsel to investigate the definition of "reasonable and necessary" in the Medicare law. No clear decision has yet been provided.

If quality of medical care for Medicare beneficiaries is to be maintained, a method of determining the most cost-effective technologies in health care is highly desirable. CEAs and cost-benefit analyses (CBAs) represent a possible group of methods. One strength of using cost considerations in general, or CEA/CBA specifically, in Medicare coverage decisions would be that the implicit rationing would become explicit. CEA/CBA methods still need to be enhanced and refined, but the process of analysis itself can help make assumptions explicit and can help identify as many costs and benefits as are feasible for consideration in decisionmaking in the health field. It is important to note that the availability of cost data is essential for this option.

A previous OTA study (353) found the use of formal, well-conducted, sophisticated CEAs or CBAs in decisionmaking in the health field is the exception rather than the rule. Adding it to the Medicare coverage decisionmaking process might be a helpful step.

Although on the surface it would appear that technology evaluations including cost criteria would be more effective in allocating resources than those without, the relative effectiveness of the two types of evaluations has yet to be demonstrated. At this time, though, it appears that CEA/CBA can at least aid decisionmaking when used in conjunction with other kinds of information (353).

Option 4: Conduct oversight hearings to improve the Medicare coverage process.

Several administrative problems pertaining to the Medicare coverage process have been identified in this report. Problems that need attention include the following:

1. the inadequate identification of emerging and outmoded technologies for coverage decisions;
2. the lack of uniformity in the implementation of national coverage decisions;
3. the timelag involved in the coverage process, including technology assessment;
4. the complex coding system and proliferation of codes; and
5. the incomplete dissemination of information.

These problems all potentially raise Medicare's costs. Their solutions may save some money and reduce the disparity in Medicare beneficiaries' coverage across the country. Numbers 2, 3, and 5, however, could actually decrease Medicare expenditures, so a detailed analysis of these problems may be warranted. The timelag, for example, could save Medicare program costs but have negative consequences on patients' health. If patients use more services in the long run because of the adverse effects of coverage delays, costs to Medicare could increase.

There are several ways of improving the identification process. Contractors have recently reported that they are receiving inquiries concerning the coverage status of new technologies from manufacturers and providers. HCFA could monitor the Food and Drug Administration's (FDA's) processes to anticipate new medical devices and

NIH's registries where new applications of procedures (e.g., percutaneous transluminal coronary angioplasty) are followed. Similar efforts in the private sector could be scrutinized.

Oversight hearings could be used by Congress to focus the attention of DHHS on problems in the coverage process. However, the law provides DHHS with the authority to make, but not to implement, coverage decisions. The coverage index appendix, other manual instructions, and intermediary lessons are usually considered interpretive rules, and as such do not have the force of law.

DHHS may need additional funds to improve its administration of Medicare coverage. Whether the savings to the program would justify the extra cost of the administrative changes that might be necessary is speculative without further study.

BROADER INCENTIVES TOWARD TECHNOLOGY

Hospital Payment

ISSUE:

How can Medicare's hospital payment system incorporate appropriate incentives for generating effective and efficient adoption and use of medical technology?

The retrospective, cost-based hospital reimbursement system under which Medicare operated from 1966 until fiscal year 1983 was significantly altered first by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Public Law 97-248) and then by the Social Security Amendments of 1983 (Public Law 98-21). The latter mandated the phasing in of a prospective, per case, hospital payment system based on DRGs.

Prior to the implementation of Medicare's DRG per case payment system, hospital payment was based on utilization of medical technologies or on days of hospital care. Such payment may provide incentives for the inappropriate use of medical technologies in hospital settings (e.g., requiring chest X-rays upon admission to the hospital and admitting patients to the hospital on Friday before Monday surgery). Per case payment is an improvement over per diem payment but still provides rewards for certain types of inefficient behavior (e.g., unnecessarily increasing admissions). Another possible method of hospital payment is capitation payment. Unlike per case payment, capitation payment offers incentives to decrease admissions. Paying by capitation would require data systems other than those currently available.

Although it is too early to evaluate the effects of DRG hospital payment, **Medicare's new hospital payment system gives financial incentives to hospitals to increase admissions and reduce lengths of stay.** Under DRG payment, therefore, some patients may be admitted to the hospital unnecessarily, others may be discharged too early, and some may not get all their elective care in one hospital stay. In addition, under DRG payment, hospitals have a financial incentive to decrease length of stay as a way of both opening beds for new admissions and decreasing the hospital's cost per stay. To the extent that a hospital's occupancy rates are low, the incentive to shorten length of stay is weakened, because the hospital will have difficulty in filling the opened beds and covering its fixed costs.

Medicare's DRG hospital payment system also provides incentives for hospitals to reduce the number and cost of ancillary services. Prior to the implementation of the DRG system, hospital administrators had financial reasons to encourage physicians to use available technologies. Under DRG payment, hospital administrators are likely to discourage physicians from using many high-cost technologies, particularly diagnostic tests that add only marginal information and may not change the course of treatment. In some cases, the substitution of low-cost technologies for high-cost technologies may result in a decline in quality of care. Thus, quality of care remains an important issue under DRG payment.

DRG prospective payment has changed the incentives provided under cost-based reimbursement for the adoption and use of medical technologies in hospitals. In general, hospitals now have greater incentives to adopt new medical technologies that reduce their costs and lower incentives to adopt technologies that increase their costs, even when the latter are worth their added costs to society. **But the incentives for the adoption of medical technology depend on the way capital costs are treated.** Thus far, capital costs are not covered by the DRG hospital payment system and are treated as pass-throughs. Treatment of capital costs as pass-throughs does not alter the direction of the incentives governing technology adoption under DRG payment as long as the effect of a new technology on total cost per case is in the same direction as its effect on operating costs. However, **for certain medical technologies, namely, those which reduce operating costs but raise total costs per case, capital cost pass-through reverses the incentives for adoption inherent in DRG payment.** Congress has recognized that capital costs are still a problem for Medicare, and the law requires DHHS to study how capital costs should be paid in connection with the DRG hospital payment system.

Innovations in medical devices, drugs, and medical techniques that improve the quality of care for the Medicare population but also increase hospital per case costs may not be as readily adopted under DRG payment as they were before. Quality is a difficult concept to define and its measurement is equally complex. Technology assessments may offer some assistance in comparisons of the quality of care afforded by different technologies. Comparisons of different measures of quality are important for national policymakers who must decide whether a particular quality-raising technology is worth its cost to society and, thus, whether it should be adopted.

Congress has provided some control over quality of care by mandating the utilization and quality control peer review organizations (PROs). Hospitals must have signed agreements with these PROs in order to receive Medicare payments. Funding for the PRO reviews will come from the Part A Medicare trust funds. The PROs will be evaluated on the basis of their individual contracts with HCFA. One of the responsibilities of the PROs will be to monitor the potential admission/discharge/readmission problem.

The development of DRGs originally was not related to payment, but DRGs were refined once they were used for payment purposes. **Although Congress has adopted DRGs for the Medicare hospital payment system, improvements of DRGs and of the payment system are still needed.** Such refinements are anticipated in light of the series of congressionally mandated studies and the Prospective Payment Assessment Commission's responsibility for recommendations on changes in DRG relative weights and categories.

The success of the DRG payment system in containing Medicare's hospital costs remains to be seen, as does its impact on the adoption and use of medical technologies. Thus, experience with other approaches to hospital cost containment is still necessary. Furthermore, the effect of a Medicare-only payment system on health care delivery is unknown. **Whether a Medicare-only DRG payment system operating in the context of a largely pass-through system for other payment can bring about the desired changes in hospital and physician behavior on which ultimate cost savings depend is largely unknown.** Thus, it would be useful to examine how all-payer systems perform.

Option 5: Encourage DHHS to support further refinement and development of case-mix measures other than DRGs.[3]

Congress has recognized the need to refine the DRGs as the case-mix measure for hospital payment by mandating several studies. Severity-of-illness measures, for example, will be studied for their applicability within the DRG system. Even with refinements, however, a DRG-based system may not be optimal, and case-mix measures that account for resource use more accurately than DRGs might be found. Examples of potential alternatives to DRGs are Disease Staging, the Severity-of-Illness Index, and Patient Management Categories (PMCs).

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[3] The background information on this option was discussed in detail in the OTA technical memorandum entitled *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343).

Disease Staging and the Severity-of-Illness Index were both designed to provide a framework for classifying diseases according to the relative severity of the patient's condition. Both have required extensive developmental work and testing, which are still underway. Use of either measure would require more data than are generally available on Medicare claims at the present time, though the staging approach can be employed by using data that are normally included in hospitals' computerized records. Neither measure has reached the point where it is suitable for widespread implementation in a reimbursement context. However, the existence of such measures, at a minimum, serves as a reminder that the present set of DRGs ultimately may not be the best system for classifying patients.

PMCs are also in the developmental stage and are being tested now. This case-mix measure differs from others, including DRGs, in that PMCs are normative. Physicians specify an optimal set of clinical care components based on a patient's clinical characteristics. This set is the basis for the relative cost weights of PMCs. The system appears unique in that it recognizes that optimal patient management should be the focus of a system that seeks to encourage efficiency.

Development of alternatives to DRGs will require continued interest and funding from DHHS. Research and demonstration projects in which these and other alternative case-mix measures can be studied and refined may need additional funding. Other studies could be mandated if necessary.

Option 6: Encourage DHHS to develop DRG price adjustment methods that result in higher DRG payment rates for those hospitals that purchase and use certain socially desirable but costly new medical technologies.

Medicare's DRG hospital payment system provides financial incentives to hospitals to purchase and use those technologies that reduce costs per case. Thus, specific policy might be required to encourage the adoption of socially desirable technologies that raise costs. Making extra payment for a DRG conditional on a hospital's adoption and use of a new technology would encourage the technology's diffusion.

Two possible mechanisms for making adjustments in DRG prices that would be conditional on the adoption of technology are reliance on hospital-initiated appeals of DRG prices and creation of new technology-specific DRGs. Either of these mechanisms could stimulate adoption of desirable but cost-raising technologies. If a new DRG with a higher rate were created specifically to pay hospitals only if they actually adopt and use a technology, the adjustment in price would clearly be an incentive to adopt.

Both of these mechanisms have drawbacks. First, reliance on case-by-case hospital appeals of DRG prices is likely to be administratively costly and cumbersome in comparison to other adjustment methods. Second, both the appeals mechanism and the creation of new DRGs would result in an effective increase in the number of DRG categories, or DRG inflation. Eventually, if the number of categories increased to significant levels, DRG payment would develop into a system resembling a fee-for-service system, because more and more categories would exist for specific procedures or services. Such a system, in turn, would destroy the incentives inherent in per case payment to minimize the utilization of services.

Conditional DRG payment adjustments would work best if limited to a few very high-cost technologies whose introduction would be strongly discouraged in the absence of such an adjustment. The majority of cost-raising technologies probably would be adequately handled through periodic reestimation of the costs of DRGs. The timeliness of reestimation is considered in Option 7.

Option 7: Amend the Medicare law to require annual reestimation *of the relative costs of DRGs.*

Congress has recognized the need for periodic adjustment of DRG prices. The law currently calls for recalibration (assigning new relative weights to DRGs or establishing new DRGs) at least every 4 years. This option offers a refinement of that mandate and differs from it in two ways: 1) it defines reestimation as a type of recalibration based on the estimation of historical relative costs of technology; and 2) it suggests adjusting the relative rates every year.

From year to year, some DRGs will experience cost-saving technological innovations; others will experience cost-raising ones. The relative prices of personnel, supplies, and other inputs will also change, with consequences for relative DRG costs. Relative DRG rates should reflect the relative costs of efficient and clinically optimal care, including appropriate use of technologies. The purpose of annual reestimation would be to keep DRG rates reasonably in line with the cost of efficient care. Annual reestimation of relative DRG rates would also encourage the rational adoption and appropriate use of medical technologies. Under the current statutory requirement, up to 4 years may elapse after the emergence of a new, fast-developing technology before the relative DRG rates would even begin to reflect the change, and the gradual adoption of new technologies would further delay the full capture of their effects in DRG prices. Implementation of annual reestimation would provide a quicker mechanism for adjusting prices to the efficient production of care.

Financial incentives for hospitals to increase their efficiency would not be weakened by frequent reestimation of relative costs of DRGs. This option focuses on *relative* prices, so it would still be in a hospital's best interest to perform efficiently. Since the reestimation would be based on average prices across hospitals, the inclusion of a large number of hospitals' cost reports in the reestimation is important so that there is a large sample size within each DRG.

The potential gains from DRG creep, or deliberately assigning a patient to a higher priced DRG to receive more payment, would diminish if DRG prices were restimated frequently. New DRG prices or weights would reflect the new distribution of patients among DRGs and the new average costs per DRG. Over time, reestimation of prices would cause the more profitable DRGs to become less profitable, and the less profitable ones more profitable. Thus, one could expect a gradual decline in the potential for "gaming" via DRG creep with periodic reestimation of DRG prices.

One advantage of frequent updates of DRG prices would be the alleviation of the lag that is already built into the current system because fiscal year 1984 prices are based on fiscal year 1981 data. The 1981 data reflect accepted modes of practice in 1981 and do not account for new technologies currently in practice. Furthermore, Medicare cost reports are available on an annual basis, so annual reestimation would require no additional data collection (at least until fiscal year 1988, when cost reports will no longer be required). Frequent reestimation of DRG prices would capture gradual changes in hospitals' costs which should result as hospitals seek technological efficiency.

If the reestimation were too frequent, however, hospitals would not be able to plan their moves toward efficiency as well as they could if they were certain of particular payments for a segment of time. Because the year-to-year changes in relative prices are likely to be small and gradual, an annual (or at most biannual) reestimation would seem to provide the optimal mix of certainty for hospital planning with the adjustment of prices for efficient production of care.

Administering annual reestimations would be slightly more expensive for Medicare than reestimation every 4 years. Not only would the process be more frequent, but the data requirements for reestimation—cost reports and patient charges—would continue indefinitely. The requirements for data collection would increase administrative costs to the hospitals, although many hospitals are likely to use the same data for internal management functions under DRG payment.

Option 8: Amend the Medicare law to strengthen controls over hospital admission rates.

Under Medicare's DRG prospective payment system, hospitals are paid by Medicare on the basis of the number of Medicare cases treated in each DRG. Thus, the DRG hospital payment system provides a strong financial incentive for hospitals to increase the number of Medicare patients they admit. One of the responsibilities of the PRO program is to monitor hospital admissions. The following suboptions are presented as possible support for the PRO regulations.

Option 8a: Amend the Medicare law to require a second deductible for rehospitalization within 60 days of the first admission.

Implementation of this option could save the Medicare program money in two ways. Currently, Medicare beneficiaries do not have to pay a second deductible for rehospitalization within 60 days of the first day of the initial admission. By increasing beneficiary cost-sharing, adopting this option would save Medicare program costs. Imposing a second deductible could also save costs by encouraging cost consciousness in physicians. Physicians would be aware of the financial burden of readmissions on their patients, and such patients might take a more active role in decisionmaking about readmissions.

Identifying unnecessary discharges and readmissions is a PRO responsibility. It is important to recognize that some readmissions are necessary. Often, elective procedures are postponed until patients are stronger and more able to withstand surgery or invasive procedures. Sometimes unrelated diseases may strike patients in short periods of time.

A drawback to the second deductible is that Medicare beneficiaries already carry a heavy financial burden for their health care. Furthermore, the amount of control patients actually can have in making decisions about hospitalization is questionable. Thus, a second deductible might decrease access to inpatient hospital care for some elderly and disabled patients. On the other hand, its effect on admissions may be low because a high proportion of the elderly have supplemental ("Medigap") medical insurance. (Of course, Medigap insurance premiums are likely to rise in response to cover the increased costs.) The strength of the incentives is unknown, because there are no empirical studies on how the elderly would respond to additional cost-sharing.

Finally, implementation of this option might actually *increase* Medicare's costs. Physicians and patients might decide to keep patients in the hospital if there is a chance that a readmission might be possible in 2 or 3 weeks.

Option 8b: Amend the Medicare law to provide a short-term outlier policy for DRG payments.

With a short-term outlier policy, Medicare would not pay the full DRG payment if a length of stay were less than a particular number of days for each DRG. Such a policy would counteract the incentive under DRG payment for hospitals to admit patients for very short stays instead of treating them on an outpatient basis. A potential benefit could be that marginally ill patients who might not require the intensive services of an inpatient hospital stay would not be admitted. A potential problem would be that such patients might be kept beyond the outlier threshold length of stay to avoid the short-term outlier payments. The strength of the incentives under this kind of policy would depend on the marginal costs of admitting a patient compared to the outlier price, as well as the hospital's influence with its admitting physicians. The effect of a short-term outlier policy on the volume of patients in each hospital or in hospitals in the aggregate is unknown.

Option 8c: Amend the Medicare law to adjust DRG payments for patient volume changes.

DRG prices are based on the assumption that hospitals' annual volumes are predictable and vary only slightly from year to year. Adjusting DRG payments to hospitals for volume changes could directly balance the financial incentive that DRG payment gives hospitals to admit more and more patients. Unusual increases in the annual number of hospital admissions could trigger a penalty charge against the hospital's total Medicare payment, or each DRG payment could be decreased by a certain amount. Thus, for example, if a hospital's volume increased 10 percent, DRG payments could be decreased by an amount reflecting the marginal costs of those additional admissions. While this payment reduction would discourage hospitals from unnecessarily increasing their admissions, the net decrease in a hospital's revenues would be relatively small.

A two-way volume adjustment imposing a penalty for unusual increases in admissions and giving a bonus for unusual decreases could be instituted. A penalty for unusual increases in patient volume could weaken the incentives for hospitals to overadmit patients. A bonus for unusual decreases in admissions could protect hospitals from the financial problems caused by population migrations. It should be noted, however, that some hospitals are inefficient or provide a lower quality of care and may experience decreased admissions for these reasons; the low-end volume adjustment might allow them to remain open when they actually should close.

Another important consideration for deciding whether to adopt a volume adjustment is the fixed-cost-to-variable-cost ratio for various hospitals. Although low-occupancy hospitals may need to increase their patient volumes in order to cover their fixed costs, large volume increases may trigger high variable costs. Thus, even without volume adjustments, the fixed-cost-to-variable-cost ratio and its relationship to the DRG payment and penalty are important.

Volume adjustment also discourages the potential for specialization of services within hospitals for the purposes of efficiency. Payment based on DRGs gives hospitals financial incentives to treat patients in those DRGs in which the hospitals are efficient and to avoid treating patients in those DRGs which lose money. Thus, consolidation of services is a potential result of the DRG payment system. Again, high- and low-occupancy hospitals would be affected differently, with fixed and variable costs important to their decisions about which patients to treat.

Option 8d: Amend the Medicare law to establish financial incentives for physicians' decisions about hospital admissions that are consistent with the incentives of DRG payment.

Decisions to admit and discharge patients and to use medical technologies during hospital stays are primarily made by physicians, although patients' decisions are certainly important. Under DRG hospital payment, physicians will probably be pressured by hospital administrators to discharge patients earlier than they previously have and to readmit patients for elective procedures. While quality assurance and utilization review programs will reinforce physicians' own inclinations to provide adequate care for their patients, financial incentives could be established to mitigate any potentially harmful pressure from hospitals. One possibility would be to pay physicians only half their fees for rehospitalization within 60 days.

A potential administrative and policy problem might arise when more than one physician is involved in a patient's care. In a case, for example, in which one physician admits a patient to a hospital for diagnosis and then, after discharge, refers that patient to a specialist for long-term treatment, it remains questionable whether a hospitalization should be counted against the patient (if Option 8a were implemented), the physician (in the case of this option), or the hospital.

Identifying readmissions would be a fairly simple task, and monitoring their appropriateness is a PRO responsibility. Difficult judgments will have to be made about which ones are unnecessary and what caused the readmission—not all complications can be predicted, nor can they necessarily be averted by additional hospital days during an initial admission. The difficulty in making such judgments could be compounded by administrative difficulties of combining Part A data on hospital admissions with Part B data on physician payment.

Option 9: Amend the Medicare law to control capital expenditures by hospitals by removing capital cost pass-throughs.

Historically, capital expenditures by hospitals have been reimbursed under Medicare on the basis of depreciation and incurred interest expenses. Under the DRG hospital payment system, at least during the 3-year transition period, capital costs will continue to be treated as pass-throughs. The pass-through method of payment for capital, which directly links the level of payment to the amount of capital investment undertaken by a hospital, does not discourage inefficient capital purchases. However, its feasibility has been demonstrated, it is fair in the sense of treating hospitals alike, and it poses no barriers to equal access to medical services.

The Social Security Amendments of 1983 (Public Law 98-21) mandated a DHHS study of alternative methods of handling capital under Medicare's DRG hospital payment system. Three methods of limiting capital payment to contain costs for Medicare were discussed in chapter 6: 1) uniform payment (flat rate) approaches; 2) hospital-specific controlled rates; and 3) if the pass-through is continued, direct regulation of capital expenditures.

If the capital pass-through is continued, capital expenditures could be regulated on a project-by-project basis. Such regulation could be implemented through certificate-of-need (CON) programs or other agencies. The political process involved in CON programs might, but would not necessarily, provide equity of access to medical technologies. Studies of the effectiveness of CON regulations in containing costs are inconclusive, and the efficiency of a process such as this is questionable. Administrative costs would be very high, and some hospitals might be unable to afford the costs associated with the application process and, thus, be impeded from making capital investments. New hospitals might not be considered because of the high cost of application and the possibility of denial.

The following two suboptions are presented as possible alternatives to capital pass-through payments under DRG payment. They are not intended to represent the entire range of methods of handling capital.

Option 9a: Incorporate a flat rate for hospital capital into the DRG rates.

The uniform payment approach would treat all hospitals or all those in a class alike, regardless of their level of capital expenditures. A flat rate for capital, whether calculated either as a fixed percentage of the DRG price or as a flat rate per bed, would encourage hospitals to provide care at the least possible total cost to the hospital. Since new technologies would be judged in terms of their impact on total costs, not just on operating costs, a flat rate would give hospitals more incentives to be efficient than the current capital cost pass-through. Hospitals would be further encouraged to specialize and join in plans for regionalization of health services.

Despite the increased efficiency of a uniform rate for capital built into the DRG rates, it would be difficult to ensure that this type of system would be fair to all hospitals. Hospitals that in the past have had lower ratios of capital to operating cost would receive more than before, while those with historically high ratios would receive less. Thus, public hospitals would probably fare better with a flat-rate system than they have in the past, at least in the short term. Multihospital systems, whose affiliated hospitals could pool capital payments and smooth out fluctuations in capital expenditures across affiliated hospitals, would also be favored. Implementing the uniform payment approach might require a difficult and costly transition period if those hospitals that have made major investments in recent years or that face them in the near future are not to be unduly penalized.

A uniform capital payment method such as a flat rate within the DRG payment would not discourage equal access to medical technologies and might help redress some current inequities because of the possibility of increased capital payments to public hospitals and others that serve low-income patients. It might, however, have a negative impact on the regionalization and specialization of services among hospitals because of the difficulty some hospitals would have in accumulating enough capital to specialize. If the population shifts, moreover, new inequities for opening and closing hospitals might appear. The question of separating capital expenditures for equipment from those for buildings should be addressed.

Making the transition from the cost-based reimbursement system to a flat rate capital payment could be difficult for hospitals. Phasing in the flat rate by reducing the proportion of capital payment that would be a pass-through over a period of time could alleviate some of the financial difficulties but would not necessarily reduce the amount of paperwork or data collection costs.

Option 9b: Build hospital-specific capital allowances into the DRG system.

To implement this option, hospital-specific cost information would be taken into account to establish a base period level of capital payment, and the payment level would be increased by an index over time. One approach would be to use the hospital's capital costs in a base year and then add a percentage for inflation. Another would be to limit capital payments to a percentage of a hospital's operating costs in each year.

Tying capital payment to a hospital's level of capital costs in a base year or to the hospital's operating costs would be efficient but might be unfair. Hospitals that were most highly capitalized in the past would be rewarded, while those with low levels of capital would forever receive low payments.

An increased administrative burden would be put on the hospitals, especially in the transition period from pass-through to hospital-specific controls. In the early years of implementation, this system would not work well for hospitals that require major capital expenditures. Perhaps for these reasons, it might be better to limit this approach to the movable equipment portion of capital, which typically has shorter lifetimes and lower variations in asset values among hospitals.

Option 10: Provide adequate resources or incentives for States to experiment with alternative hospital payment systems, especially those involving all payers.

In States where Medicare is the only third-party payer using prospective payment, hospitals will have incentives at best to shift costs to other payers and at worst to treat patients differently depending on their insurance. Savings to the Medicare program may not offset these other social costs. Furthermore, a Medicare-only hospital payment system such as the current one may not provide sufficient leverage to lower the annual rate of increase in hospital costs. Further experimentation with hospital payment systems would be desirable to learn which methods of cost containment save the most money to Medicare and society as a whole.

The Social Security Amendments of 1983 (Public Law 98-21) encourage States to experiment with payment systems that cover multiple third-party payers and differ from DRG payment by requiring the Medicare program to participate in any State-legislated prospective payment program that covers at least 75 percent of the State's population; makes provisions for competitive health plans; assures the Federal Government that access to hospital care for Medicare and Medicaid beneficiaries will not decline; and assures the Federal Government that hospital costs will not be higher under the State program. Four States—Maryland, Massachusetts, New Jersey, and New York—already regulate all payers in their hospital prospective payment systems and have Medicare waivers. Other States will be examining the effectiveness of the payment systems in these four States with Medicare waivers and others experienced in containing hospital cost increases. The goal of this option would be to encourage the efforts of several State legislatures that are working on this issue.

While all-payer systems would increase the payment system's leverage over the hospital industry and reduce hospitals' tendencies to shift costs among payers, such systems have been criticized for their potential to inhibit competition. According to this viewpoint, regulation precludes market forces from exhibiting their desired effects and thwarts innovation. How much health care delivery systems *should* respond to market forces is debatable.

Changes in hospital behavior in response to the all-payer system incentives are predicted to range from increasing efficiency through specialization and interhospital cooperation to closing their doors (6). The viability of particular hospitals can be guaranteed or threatened, depending on the goals of the particular State payment system. For example, in New York, the capital pooling system was established to save a number of inner-city hospitals; and in New Jersey, several small hospitals have closed or merged at least in part because they could not earn enough money through DRG payment (47).

There is empirical evidence from New Jersey that vertical integration has been encouraged by the DRG all-payer system there (75). As long as only hospitals are under the all-payer system, there will be incentives for them to branch out and open separate home health agencies, nursing homes, and satellite outpatient clinics. They will have to continue to compete with each other for physicians and patients.

All-payer prospective payment systems are not the only approaches that may be attempted by the States. Other approaches to the control of hospital costs, however, have significant limitations. Two of these methods, increasing the patient's responsibility for cost-sharing and limiting providers through contracts between Medicare and hospitals, were examined in chapter 6. Factors such as the patient's relative lack of power and information to make informed decisions about the use of technologies in hospitals and the apparently strong preference of the elderly for supplemental medical insurance regardless of its cost imply that beneficiary cost-sharing for hospital services is not likely to be as effective in altering the patterns of use of hospital technologies as desired. And although contracting might save Medicare dollars, such contracting would represent an abandonment of the principle of beneficiary freedom of choice of provider on which Medicare was built and would force subsidies of hospital care from other payers.

Option 11: Consider ways to extend the DRG prospective payment system to payers other than Medicare (e.g., Medicaid) without relying on State waivers.

This option differs from the previous one because this option addresses the current DRG prospective payment system, whereas the previous option sought alternative systems. The desirability of this option depends on the effectiveness of DRG payment in encouraging the appropriate adoption and use of medical technology and in containing Medicare costs. The effectiveness of DRG payment is currently unknown.

As discussed in the previous option, a multipayer system would increase the payment system's leverage over the hospital industry. A multipayer system would also diminish hospitals' opportunities to shift costs from one payer to another, although multipayer systems need not pay all payers the same price.

The clearest technical problem with extending the current DRG-based hospital payment system beyond the Medicare program is that DRG prices have been based almost exclusively on Medicare data. Comparable Medicaid data bases are not available, and the Medicare and Medicaid populations are so different that the use of Medicare-generated DRG prices for the Medicaid population would be unfair. Even if both data bases were available for recalculation of DRG prices, the problem of within-DRG variation in costs per patient would be exacerbated because of the diversity of populations.

It should also be noted that many State Medicaid agencies are experimenting with methods of prospective payment. Potential refinements for the Medicare system could come from these experiments.

Physician Payment

ISSUE:

How can Medicare's physician payment method be used to improve the incentives for appropriate technology adoption and use?

Physicians can influence both the number of patient visits and the use of a variety of technologies, especially diagnostic tests. Furthermore, **the ways in which physicians are paid can influence physicians' adoption and use of medical technologies.** Physicians who are paid on a fee-for-service basis have incentives to see more patients more often and to provide more technologies. Physicians (or practice plans in which they participate) paid on a capitation basis would want to increase the number of their patients but would have incentives to keep the number of visits low (or nonexistent) and to use particularly cost-effective technologies. Physicians' incentives under a fee schedule system would depend on the particular type of schedule adopted. Under fee schedules based on patient visits, physicians would have an incentive to schedule more visits but would have a disincentive to use a large number of technologies (particularly those whose costs are high in relation to the fee per visit received). If the fee schedule were based on episodes of illness, physicians would have incentives to treat for more episodes but would want to keep patient visits for each episode and the use of costly technologies at a minimum.

Excessive adoption and use of medical technologies are sometimes incorporated into medical practice through habitual behavior of physicians and because the health care system contains few disincentives for these practices. Excessive use occurs within the norms of medical practice and is

evident across the spectrum of technologies available to physicians.

Physicians are motivated by their training to do all they can for their patients, and generally they have not—in the past—had to be concerned about the costs of the care they provide. Indeed, there have been economic incentives for physicians to increase demand for health care services. These factors, singly and combined, often result in overuse of medical technologies.

Two types of changes in Medicare's physician payment method could contain costs for the Medicare program and help rationalize the adoption and use of medical technologies: 1) requiring beneficiaries to assume more responsibility for their health care costs, either through increases in patient cost-sharing or reductions in the types of services covered; and 2) imposing restraints on the amount and type of payment to physicians. The options presented below are grouped according to these two categories—cost-sharing by Medicare beneficiaries and changes in physician payment methods. **Either type of change could result in cost savings for the Medicare program, but each type would have different effects on the adoption and use of medical technologies and on access to medical care by Medicare beneficiaries.** The options presented do not always relate directly to medical technology, but they are important because of their indirect effects on technology. Changing Medicare's voluntary physician assignment policy could strengthen the effect of implementing some of these options.

Option 12: Amend the Medicare law to increase beneficiary cost-sharing for Part B services.

Several methods of cost-sharing were explored in chapter 7. Increasing the premium for Part B benefits would increase revenues for the Medicare program, but the evidence suggests that premium cost is too far removed from the use of medical services to alter patterns of use. This change would spread the burden of costs among many beneficiaries without regard to their use of the medical care system, and demand for medical technologies probably would not be affected. Increasing the deductible for Part B, again, might not reduce the use of services. Medicare beneficiaries often have chronic diseases and require multiple physician visits.

Coinsurance raises financial barriers each time medical services are sought. Increasing Medicare's Part B coinsurance requirements would have a more significant effect on the demand for medical technologies than would a deductible. Part B beneficiaries are already responsible for a 20-percent coinsurance payment for assigned care and even more for nonassigned care. Modest increases in coinsurance requirements would probably have little effect, beyond the incentives already accompanying current coinsurance requirements, on patient behavior. Large increases, on the other hand, would probably result in fewer visits to physicians but might also result in a reduction in access to necessary medical care, especially for the lower income elderly who are not eligible for Medicaid.

In summary, greater cost-sharing by Medicare beneficiaries under Part B could help contain Medicare program costs, in part by a shifting of costs to beneficiaries and in part through some resulting decrease in patient visits. It is unclear that all appropriate technologies would be provided with greater cost-sharing, however, because Part B beneficiaries might have to forgo some necessary medical care.

Option 13: Discourage Medicare beneficiaries' purchase of private supplemental ("Medigap") insurance.

Private insurance companies have offered, and many Medicare beneficiaries have purchased, supplemental ("Medigap") insurance policies to cover, at least partially, patients' out-of-pocket medical expenses. Noting that the type of extra first-dollar coverage that Medigap policies provide partially nullifies the intended effects of Medicare's deductible and coinsurance requirements on use of medical services, some observers have suggested taxing Medigap policies to make their purchase less attractive. A principal objection against taxing Medigap insurance is fairness, because the general population's health insurance policies retain their tax advantages. If this option were adopted, the constitutionality of selective taxation would most likely be challenged.

Because elderly people already pay about one-third of their medical expenses out-of-pocket and need more medical care than younger people, this option raises two broad issues: 1) whether Medicare should become the sole medical insurer for the elderly rather than providing a floor of insurance coverage as it does now, and 2) whether the Medicare program will provide adequate insurance coverage, especially in view of present cost-containment efforts.

Option 14: Place further limits on payment to physicians under Part B of Medicare.

Methods of limiting payments to physicians fall into two categories: 1) limits on allowable physician fees, and 2) the use of fee schedules. Both methods raise the issues of assignment of claims and changes in coding of procedures.

Option 14a: Amend the Medicare law to place a ceiling on allowable physician fees under Medicare.

The Medicare Economic Index currently limits the rate of physicians' fee increases to the rate of their cost increases. Other types of caps that could be imposed include freezes on physician payment levels for a specified period of time and percent limitations on the annual rate of allowable fee increases.

A cap on physician payment levels by Medicare is unlikely to change overall reimbursement to physicians, because physicians could increase patient visits, increase the number of technologies provided to each patient, and shift to a higher priced mix of technologies. Because it is unlikely that physicians would charge less than the cap, such a cap would be effective in containing program costs only if it were set low. A low fee cap, however, would result in widening the gap between fees paid by Medicare (allowed charges) and those paid by private patients (billed charges). Thus, fewer physicians would be likely to accept assignment. With less assignment, Medicare beneficiaries would have to pay an even greater share of their total health costs. Program savings would accrue at the expense of patients, and increased cost-sharing might result in decreased access to needed medical care.

Option 14b: Move to fee schedules for physician payments under Medicare.

Current limitations on increases in allowable charges are slowly turning Part B physician payments into de facto fee schedules, but historical specialty and geographic differences in fee levels that have developed under the fee-for-service system of payment remain. Cost-based fee levels could be developed, but they would require a data base that relates costs to charges in some rational fashion. The difficulty in developing such a data base should not be taken lightly.

Payment through fee schedules would necessitate a reformulation of the diagnostic and procedural codes for physician services that are currently used by the Medicare program. The number of procedural and diagnostic categories in these codes has increased by the thousands since the onset of Medicare and Medicaid. The large number of categories increases the likelihood of incorrect coding, and the availability of numerous categories to choose from in the billing process makes it possible for physicians to bill for higher priced services than those actually provided.

Furthermore, since the existing fee and price system provides financial incentives for the use of "technology-intensive" medical care, one long-range objective in developing fee schedules might be an overall review of the relative values of all procedures. The fee system could then be revised in such a way that technology-oriented services, such as performing diagnostic tests and surgical procedures, might be valued neutrally with cognitive services, such as taking medical histories and providing patient counseling. Current fees and payment methods favor the technological patient services over the cognitive.

Before fee schedules are developed, packages of physician services, possibly designed to complement existing DRGs for hospital care, could be developed. Inpatient surgical services would be one logical starting point. Other physician services could also be included. For example, DRG-based payment to physicians might be applied initially only to acute inpatient care, then extended to include physician services in skilled nursing facilities, and then to ambulatory care for those diagnostic categories where such an inclusion was found to be appropriate and feasible. Coordinating physician and hospital payments is important, because there is an incentive under DRG hospital payment to move services out of the hospital settings. An advantage of a fee schedule for physicians would be a probable reduction in inpatient hospital physician consultations and possibly even reduced length of stay. A disadvantage is that it would depend on inpatient care as the starting point, leaving other ambulatory visits outside the system, at least at first.

Option 15: Change Medicare's claim-by-claim voluntary physician assignment policy.

Medicare's current policy of allowing physicians to decide whether or not to accept assignment on a claim-by-claim basis allows costs to be shifted from the physician to Medicare beneficiaries. Although such cost shifting may decrease demand for medical technologies, it may also decrease access to necessary medical care. Changing assignment policy would strengthen Option 14 and suboptions.

One type of change in assignment policy is to make assignment mandatory, so that physicians are not paid at all by Medicare if they refuse to accept assignment. Under mandatory assignment, beneficiaries would have greater incentives to seek out physicians who accept assignment, because they would assume all of the costs of nonassigned care (except for any portions covered by a Medigap policy). Physicians would also have to weigh the financial impact of losing their Medicare income altogether versus accepting the payment levels set by Medicare.

Thus, mandatory assignment provides an incentive for cost-conscious behavior in both patients and their physicians, whereas under present assignment policy, most of the burden of cost savings falls on Medicare patients. Mandatory assignment could reduce access to medical care for Medicare's beneficiaries, however, because they would be responsible for payment of charges for nonassigned care. At least under current assignment policy, Medicare pays 80 percent of allowed charges for nonassigned care.

An alternative to establishing a mandatory "all-or-nothing" assignment policy or maintaining current assignment policy is for Medicare to pay less for nonassigned than for assigned care. This might spread the burden of cost-sharing more equitably between patients and their physicians and provide significant incentives to both groups to be more conscious of costs. Reduced payment could be implemented either by further reducing allowable charges for nonassigned versus assigned services, or by increasing the coinsurance requirement for nonassigned care (e.g., from 20 to 50 percent). Either approach could be designed to achieve similar savings for the Medicare program, but reducing allowable charges would be directed at physicians, while increasing the coinsurance requirement would be directed at patients.

Patients may ultimately bear most of this shift in costs in either approach, however, because of their liability for the difference between billed and allowed charges for nonassigned care. An additional adjustment under this alternative could be to prohibit billing by physicians for the difference for nonassigned care, and payment could be made directly to the physician for allowed charges (minus the patient's coinsurance share). Under current payment for nonassigned care, allowed charges are computed and 80 percent paid to the patient, not to the physician, who must then collect from the patient.

Most, if not all, payment changes in the Part B program are likely to place additional financial burdens on patients. Some observers suggest that the additional burden (which Medigap insurance moderates) is desirable, because it gives patients incentives to behave in a cost-conscious manner when seeking medical care. Patients must have the information on which to make such informed decisions. Thus, even if none of the financing and assignment options is undertaken, it would be desirable for patients to have more information. Medicare beneficiaries could be given information on their payment responsibilities, what assignment means, the relative charges of physicians in their areas, and names of physicians who accept assignment.

Option 16: Require review of physicians' services.

Option 16a: Encourage the development of a review program for physicians' services.

Professional Standards Review Organizations (PSROs), which concentrated their review on the appropriateness of hospital admissions and lengths of stay, were statutorily replaced by PROs in 1982 (Public Law 97-248). Under Medicare's DRG hospital payment system, PROs will have the added responsibilities of reviewing the validity of diagnostic information provided by hospitals (DRG verification) and the appropriateness of moving patients from hospitals to less intensive care settings such as nursing facilities and home health care.

DRG payment provides financial incentives to reduce the unnecessary use of ancillary services in hospitals. This option would address the fact that similar disincentives for the excessive use of medical services in physicians' offices and other ambulatory care settings are lacking. While there is evidence that physicians do respond to restraints on physician payment levels by increasing the number of services they provide and shifting to a higher priced mix of services (153,275), however, one problem in identifying excessive use on a procedure-by-procedure and physician-by-physician basis is in differentiating between normal and excessive provision of medical care.

Under Public Law 98-21, HCFA is required to study the possibility of extending DRG payment to physicians' services. The resulting information will, in essence, reflect norms of care on which DRG-based prices could be computed. Such norms of care might also be used to extend PRO activities to inpatient physicians' services. Similarly, information for extending DRG payment to ambulatory care might be used to develop review systems for office-based care. The costs of conducting such an extensive review program, however, would be substantial.

Option 16b: Require or pay for second opinions in elective surgery.

Voluntary second surgical opinion programs generally have had low participation rates. In HCFA's two demonstration programs, for example, only 1.2 and 0.3 percent of Medicare beneficiaries who had surgery participated in the programs and sought second opinions, despite waiver of deductibles and coinsurance for the second opinion (127). Because of low participation rates, the potential savings from voluntary programs are not great.

On the other hand, there is growing, though not comprehensive, evidence that mandatory second surgical opinion programs reduce the amount of elective surgery. The reduction takes place in part because the first surgeon is aware that the patient will need a second opinion and in part because patients tend to follow the second surgeon's recommendation.

As an alternative to an across-the-board, mandatory program, a mandatory program could be initiated for a few elective surgical procedures. The procedures included could be slowly expanded if the original program leads to cost savings. Monitoring the impact of this option, if implemented, would thus be very important.

Alternative Approaches to Changing Incentives

ISSUE:

What broad approaches, other than those *directly* involving Medicare's payment mechanism, could be used by Medicare to encourage the appropriate adoption and use of technology?

Most cost-containment strategies that rely on the existing Medicare program structure emphasize restraints on payments made to hospitals, physicians, and other providers, augmented by utilization and other types of review programs. Such approaches are complemented by efforts to increase beneficiary cost-sharing. Other approaches that may be more feasible or desirable include changes that must involve the general health care system but that Medicare could embrace and changes in the structure of the Medicare program itself.

Long-range cost containment in the Medicare program is limited by the kinds of health care delivery systems available and the influence that Medicare financing can have on the settings and kinds of technologies provided. In recent years, the Medicare program has granted exceptions to specific alternative types of care (e.g., freestanding ambulatory surgical centers) and encouraged the development and evaluation of alternative delivery methods (e.g., preferred provider organizations) through demonstration programs. Thus, Medicare's efforts in developing competition with the types of care predominantly available have been to identify and encourage other types of provider practices and modes of delivery. **In the long run, it is hoped, the use of alternative sites and organizations will lead to cost-effective health care by encouraging competitive behavior among providers.**

A complementary approach to increasing competition among providers involves moving from the current Medicare program structure to a system in which a variety of types of health insurance coverage would be made available to Medicare beneficiaries. The most discussed possibility is the use of vouchers, wherein persons eligible for Medicare would receive a specified amount of money to purchase health insurance from the marketplace. The assumption is that beneficiaries would be encouraged to select delivery systems that offer the best benefits for the least amount of money. To the extent that health maintenance organizations (HMOs) or preferred provider organizations (PPOs) can achieve this goal, these organizations would be selected.

Competition can occur both at the point of insurance and at the point of service delivery. In both cases, payment by capitation is believed to increase competition. A voucher, with its fixed dollar subsidy, is actually a capitation method of payment for total medical care (both inpatient and outpatient). The beneficiary who receives the voucher may benefit from competition among plans. The beneficiary could purchase traditional fee-for-service insurance or could select a plan such as an HMO that accepts a capitated payment per enrollee. Important decisions regarding competition for policymakers in the Medicare program include: 1) the relative emphases to be placed on the insurance versus the alternative delivery system approach, and 2) the pace of adopting the various competitive approaches into Medicare. To increase the capability of Medicare to embrace the various competitive approaches, however, the program could undergo an administrative change—merging Parts A and B.

Option 17: Move toward a capitation payment system for Medicare.

The extent and pace of changing the Medicare program to capitation payment depend on the capacity of the health care system to provide alternative sites and organizations of medical care and on Medicare's leverage in promoting alternative delivery methods or requiring that they be substantially available. In one sense, there is a chicken-or-egg question—i.e., must substantial changes in the health delivery system come first, or is it the financing leverage of programs such as Medicare (and its effects on the general health care system) that will lead to the desired health system changes?

Under current Medicare policy, the implicit assumption is that health care system changes must come first. This assumption is reflected in Medicare-supported demonstrations of alternative delivery methods and Medicare's service-by-service adoption of alternative methods (e.g., ambulatory surgery centers, special provisions for HMO participation). This assumption is also present in discussions among policymakers on Medicare vouchers. A voucher program may involve mandatory or voluntary participation. A voucher could be completely voluntary and allow beneficiaries to reenroll in Medicare, it could require that the decision to opt out of Medicare be permanent, or it could trigger mandatory participation if and when more than half of the beneficiaries choose vouchers. It is believed, however, that the implementation of mandatory vouchers for Medicare is not politically feasible (336). In other words, there is reluctance to end the current Medicare program per se and place the burden on beneficiaries to see if the market will respond.

Under voluntary voucher proposals, the policy is to provide enrollees with incentives to seek more cost-effective care, such as through HMO- or PPO-type organizations. If voluntary vouchers succeed in stimulating alternative systems, then the current Medicare program would slowly be replaced.

A voluntary voucher system for Medicare could be implemented without fundamental changes in the basic Medicare program. Replacement of the current Medicare program would depend on the amount of use of the vouchers, which in turn would depend on the capacity of the health care system to provide cost-effective alternatives to present Medicare benefits.

In sum, encouraging competitive approaches into the Medicare program can proceed by providing enrollees with the opportunity to opt out of the basic program, or by transforming the basic payment program itself into a competitive mode. A Medicare program with capitation as the insurance mechanism might be initially implemented in urban areas, particularly urban areas with competition for patients and with substantial availability of prepaid services. The pace at which a voucher-only approach might be implemented has already been explored by the several bills introduced in Congress. A cautious pace would be to implement voluntary vouchers as a first step with periodic opportunities for reenrollment in Medicare.

Option 18: Merge Parts A and B of Medicare.

The separation of the Hospital Insurance portion of Medicare (Part A) from the Supplementary Medical Insurance portion (Part B) is inefficient and allows incentives for the inappropriate provision of technologies to persist. Because of duplication of administration in the two parts, administrative costs to Medicare are probably higher than necessary. In addition, the fiscal separation, wherein Part A is financed through a payroll tax and Part B through premiums and general revenues, also seems wasteful.

Merging Parts A and B could ameliorate the current revenue problems faced by Medicare. One proposal (84) would substitute a comprehensive, integrated set of benefits for current separate sets under Parts A and B. The benefits would be paid from a single trust fund formed from the Hospital Insurance (HI) Trust Fund and the Supplementary Medical Insurance (SMI) Trust Fund. Revenues would come from a combination of the current HI contributions, the general revenues projected for SMI expenditures, and new income-related beneficiary premiums.

Currently, parallel data systems and administrative mechanisms for Parts A and B do not allow easy cross-referencing by patient or provider. This problem is important because of providers' efforts to shift costs from one part to the other (usually A to B). Some medical technologies have been covered under both parts, but because of differences in which part paid for their use at which time, facilities covered under one part or the other have duplicated equipment unnecessarily. Such duplication results in facilities and equipment that remain idle and raise prices in order to cover fixed costs. If there were one type of coverage and one payment source, at least some of this duplication and subsequent cost shifting could be avoided.

A merger of Parts A and B would allow Medicare beneficiaries to participate more easily in alternative organizations of care. A merger would also facilitate expansion of the DRG payment system beyond the inpatient hospital setting. For example, in the future, the DRG could be defined on the basis of an "episode" of care under the joint purview of Parts A and B. The definitional difficulties could be substantial, but so could be the payoffs in efficiency, cost control, and appropriate medical technology adoption and use (201).

The transition from Part A and Part B to an integrated system would be complex. Data systems would have to be merged, and intermediaries and carriers would have to negotiate to be single Medicare contractors. Once integrated, however, the system could be more efficient, less administratively burdensome to hospitals, and less costly to society.

Appendixes

Appendix A.—Method of the Study and Case Studies

This assessment of "Medical Technology and Costs of the Medicare Program" was preceded by a 2-month planning effort that identified areas on which to concentrate and established a tentative study approach. The planning phase took place in April and May 1982, and resulted in a study proposal for the full assessment.

The full assessment began on June 1, 1982. One of the first tasks undertaken was the selection of the advisory panel. Most of the studies undertaken at OTA rely on the advice and assistance of an advisory panel of experts. The advisory panel for a particular assessment suggests source materials, subject areas, case studies, and perspectives to consider; assists in interpreting information and points of view that are assembled by OTA staff; and suggests possible findings and conclusions based on the accumulation of information produced by the study. The panel members review staff and contract materials for accuracy and validity, discuss policy options of the study, and present arguments for and against the options and conclusions. They do not determine the report's final form, however, and are not responsible for its content, direction, or conclusions.

The advisory panel for the present assessment consisted of 20 experts with backgrounds in health policy, hospital administration, health economics, medicine, health insurance, State- and Federal-level Government, industry, and academia. Several panel members also represented consumers of the Medicare program. The panel was chaired by Stuart Altman, Dean of the Florence Heller School of Brandeis University (in December 1983, Dr. Altman became chairman of the congressionally mandated Prospective Payment Assessment Commission).

The first panel meeting was held on October 22, 1982. Panel members discussed the overall study plan for the assessment based on the proposal and preliminary modifications and helped OTA staff refine the goals for the project. The panel examined the project boundaries and definitional issues and was key in sharpening the study's focus. The panel was also helpful in reviewing the primary issue areas to be covered and in providing suggestions of individuals and organizations to contact for information and assistance. Case studies of four medical technologies that were specifically requested by Congress were discussed, and the panel provided ideas for possible additional cases. The case study approach was intended to provide additional (e.g., efficacy, safety, and costs) information on specific medical technologies in order to analyze their possible effects on Medicare. The requested technical memorandum on the proposed use of Diagnosis Related Groups (DRGs) as Medicare's hospital payment method was also discussed.

Following the panel meeting, contracts were let for some of the additional case studies. Drafts of the first three case studies were received by OTA staff and subsequently mailed out for the review. This process involved the advisory panel and 50 to 80 additional reviewers, depending on the case study. In addition, OTA staff prepared staff papers on the main issues of the assessment. A draft of the technical memorandum on DRGs was also prepared by the staff and sent to the panel for their review. Only 2 weeks after the first draft of the technical memorandum was completed, the Social Security Amendments of 1983 (Public Law 98-21) mandated a change in Medicare's hospital payment system to a prospective system based on DRGs. A decision was made to focus the technical memorandum on implications for medical technology under DRG payment. Previously, the focus had been on whether a DRG system would be appropriate. Finally, during this period, the case study on alcoholism treatment was also completed. It was released by the Senate Finance Committee, Subcommittee on Health in March 1983.

The second panel meeting was held on March 22, 1983. At that meeting, progress of the study was reviewed, and the panel explored modifications in the emerging conceptual approach of the project. Considerable time was spent discussing ways to analyze and synthesize the material that had been collected. The panel also provided comments on the technical memorandum, the case studies, and OTA staff papers.

In July 1983, the technical memorandum on DRGs, entitled *Diagnosis Related Groups and the Medicare Program: Implications for Medical Technology,* and the case study on therapeutic apheresis were completed and released by OTA. Additional case studies were received from contractors and mailed out for review. In August 1983, the case study on the variations in hospital lengths of stay was completed and released by OTA. The staff also prepared a first draft of the main report for the panel's review.

The third and final meeting of the advisory panel was held on August 2, 1983. The primary focus of the meeting was on the draft of the final report prepared by OTA staff. The panel identified its strengths, weaknesses, and omissions and also defined areas for developing policy options for congressional consideration.

The first draft of the main report was revised by OTA staff to reflect the extensive suggestions and comments of the advisory panel. The second draft was then sent for a further round of review by a much broader range of experts in a diversity of settings: Federal agencies, private and nonprofit organizations, academic institutions, practicing health professionals, and other selected individuals. Altogether, more than 200 individuals or organizations were asked to comment on drafts of the main report, the technical memorandum, or individual case studies of this assessment. The second draft of the main report, containing policy options, was sent for review to approximately 90 individuals. After appropriate revisions based on comments received were made, the report was submitted to the Technology Assessment Board.

This project resulted in a number of documents: the main report, of which this appendix is a part; a technical memorandum on DRGs; and six case studies on specific medical technologies:

- *The Effectiveness and Costs of Alcoholism Treatment:* Leonard Saxe, Denise Dougherty, Katharine Estes, and Michelle Fine. Requested by the Senate Committee on Finance; Subcommittee on Health.
- *The Safety, Efficacy, and Cost Effectiveness of Therapeutic Apheresis:* John C. Langenbrunner (Office of Technology Assessment). Requested by the Senate Committee on Finance; Subcommittee on Health.
- *Variations in Hospital Length of Stay: Their Relationship to Health Outcomes:* Mark R. Chassin. Requested by the Senate Committee on Finance, Subcommittee on Health.
- *Intensive Care Units (ICUs): Costs, Outcomes, and Decisionmaking:* Robert A. Berenson.
- *Effectiveness and Costs of Continuous Ambulatory Peritoneal Dialysis (CAPD):* William B. Stason and Benjamin A. Barnes. Requested by the Senate Committee on Finance and its Subcommittee on Health.
- *The Cost Effectiveness of Digital Subtraction Angiography (DSA) in the Diagnosis of Cerebrovascular Disease:* Matthew Menken, Gordon H. DeFriese, Thomas R. Oliver, and Irwin Litt.

Several contractors' reports were also prepared. The main report, the technical memorandum, and the case study on apheresis were prepared by OTA staff. The remaining case studies were commissioned by OTA, performed under contract by experts, and reviewed extensively under the direction of OTA.

The case studies are part of OTA's Health Technology Case Study Series. The case study selection process involved OTA staff and consultations with the congressional staffs, the advisory panel for this assessment, the Health Program Advisory Committee, and other experts in various fields. Four of the case studies were specifically requested by congressional committees. The remaining two were selected to provide information and ideas for the main report and to serve as individual analyses of particular issues and technologies. Like this report, the case studies and the DRG technical memorandum are available through the U.S. Government Printing Office.

Appendix B.—Acknowledgments and Health Program Advisory Committee

The development of this assessment was greatly aided by the advice and review of a number of people in addition to the Advisory Panel and the Health Program Advisory Committee. OTA staff would like to express their appreciation especially to the following individuals:

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*Until April 1983.
**Until March 1984.
***Until October 1983.
****Until August 1983.

Appendix C.—Selected Activities in Medical Technology Assessment

Introduction

Medical technology assessment in health policy today typically refers to an evaluation of the efficacy and safety, and sometimes costs, of medical technology. Medical technology assessments are a source of information needed by government officials in formulating legislation and regulations, by health professionals in managing patients, by industry in developing products, by private insurers in creating benefit packages, and by consumers in making personal health decisions (359). Furthermore, medical technology assessments can yield information for hospitals functioning under Medicare's new Diagnosis Related Group (DRG) hospital payment system.[1]

Currently, there are numerous activities in medical technology assessment. Multiple participants from both the public and private sector perform or use medical technology assessments (359). However, there is little, if any, coordination among the various organizations, and because of a lack of funds, many organizations neither assess as many technologies nor perform as comprehensive assessments as they desire. Assessments are used for different purposes, including coverage, payment, purchasing, and management decisions. The focus of this appendix is on assessments made or used for coverage purposes.

In the past 2 years, the private and nonprofit sectors have increased their involvement in assessing medical technology. However, many of their assessments are limited to specific organizational objectives and have limited value for national policy decisions. Safety and efficacy criteria are usually used in technology assessments; economic, legal, social, and ethical criteria are sometimes used.

Public Sector Activities

OTA has estimated that Federal expenditures on evaluating health technologies in general are approximately $200 million a year (361). Only a small fraction of this amount is spent for evaluating medical technologies specifically to determine their eligibility for Medicare payment. By way of contrast, it is interesting to note that fiscal year 1982 reimbursement for Medicare services totaled $50.9 *billion* (135).

Currently, the body with explicit responsibility for evaluating selected medical technologies to assist the Health Care Financing Administration (HCFA) in determining what diagnostic and therapeutic techniques ought to be covered by Medicare is the Office of Health Technology Assessment (OHTA), of the National Center for Health Services Research in the Public Health Service (PHS).[2] OHTA's budget for fiscal year 1983 was approximately $1 million.

The Medicare program has called on PHS to provide technical medical advice for making coverage decisions since the late 1960's. The coverage advice process established initially was a loosely structured one, relying mainly on informal contacts with experts at the National Institutes of Health (NIH) or medical specialty societies for opinions about the safety and effectiveness of medical technologies. In 1977, the Administrator of HCFA and the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) formalized the PHS role in providing advice through the Office of the Assistant Secretary for Health.

In recent years, the increasingly rapid development and use of sophisticated and expensive medical technologies has increased the number and complexity of Medicare coverage determinations. Thus, Congress passed the National Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (Public Law 95-623). That act established the National Center for Health Care Technology (NCHCT).

One of NCHCT's mandated assignments was to provide scientific/medical assessments to HCFA on Medicare coverage for specific medical procedures and technologies. The agency's overall mission, however, was much broader: it was to "stimulate increased scrutiny of new and existing health care technologies to insure that their safety, efficacy, cost-effectiveness, social, ethical and economic impacts are more completely explored" and to encourage the "rapid dissemination of newly developed health care technologies which have proved their worth in terms of safety, efficacy, (and) cost-effectiveness." NCHCT's staff was officially limited to never more than 20, but "creative management" by its director, Dr. Seymour Perry, enabled the center to obtain the services of 39 individuals (45). In December 1981, however, NCHCT ceased to function because of a lack of congressional funding.

OHTA, formed as NCHCT's successor, has been assigned a variety of duties (see table C-1). Generally, however, its activities have been confined to evaluating

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[1] For more information on DRGs, see OTA's July 1983 technical memorandum *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical Technology* (343).

[2] Despite the similarities in their names, the Office of Health Technology Assessment (OHTA) and the congressional Office of Technology Assessment (OTA) are two different offices.

Table C-1.—Activities of the Office of Health Technology Assessment (OHTA)

- Provide national leadership, coordination, and administration of a comprehensive program for health care technology assessment and transfer to improve the quality and reduce the cost of medical care
- Establish criteria for public and private organizations and individuals both within and outside OHTA to identify the critical technologies to be assessed
- Administer a program of assessments of health care technologies which take into account their safety; efficacy; cost effectiveness; and social, ethical, and economic impacts
- Make recommendations on health care technology issues in the administration of the laws under the Assistant Secretary for Health's jurisdiction, including preparation of the PHS position regarding appropriateness of Medicare coverage of health care technology
- Publish and disseminate the information obtained as a result of activities supported by OHTA, and undertake programs to develop new and improved methods for making such information available
- Provide technical assistance and consultation to organizations and individuals within and outside DHHS engaged in or concerned with the results of health care technology assessments, research, evaluations, and demonstrations
- Coordinate PHS research, evaluations, and demonstrations relating to the assessment of health care technology undertaken and supported by DHHS components.

SOURCE: *Federal Register* 48(13):2444, Jan. 19, 1983.

technologies in response to requests from HCFA. When HCFA has a simple inquiry about the regulatory and research standing of a particular technology, the staff of OHTA provides background information obtained from other PHS agencies, including the Food and Drug Administration (FDA), NIH, the Centers for Disease Control (CDC), and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

HCFA may also request full assessments from OHTA. OHTA's assessment process, which involves synthesizing the available information about a technology and transmitting the results to HCFA, requires 12 to 18 months for completion. As of June 1983, OHTA had a backlog of 12 months or more on 23 technologies requiring assessment—some from 1979 (211). OHTA completed 26 assessments in 1982. The OHTA Director reported that as of June 1983, 16 assessments had been completed, 30 assessments were in progress, and 40 were expected to be completed by the end of the 1983 fiscal year (211).

In performing a full assessment, the OHTA staff first reviews the coverage issue with HCFA, clarifies the original request, and defines appropriate questions. It also initiates a literature search and data collection effort, gathering information from a wide spectrum of sources. Working under a philosophy that it should hear from all interested parties, OHTA advertises an impending assessment in the *Federal Register*. Although notices and advertisements regarding particular coverage issues also appear in professional and trade publications, notices in the *Federal Register* are PHS's primary access to the "general public" and are used to obtain the views of a broad mix of interested parties. Responses to such notices have generally come from industry and physicians.

For available scientific information, clinical trial data, bibliographic materials, and other relevant materials, OHTA solicits the advice and assistance of Federal agencies such as NIH, FDA, ADAMHA, and CDC. Each agency has developed a formal plan for responding to such evaluations. Furthermore, PHS routinely announces the assessment through DHHS's Technology Coordinating Committee, which informs other interested Federal agencies. OHTA also contacts the Council on Medical Specialty Societies, the organization representing all medical specialty societies, as well as the relevant specialty societies for information on the specific technology (or in some cases, a list of technologies) being considered.

The OHTA staff then analyzes and synthesizes the medical and scientific evidence and professional opinions collected. OHTA's assessment, primarily of the safety, efficacy, and clinical effectiveness, of the technology in question is conducted according to specific criteria (399). The types of acceptable information range from qualified medical opinions derived from personal experience, to well-designed clinical studies, to controlled clinical trials. Although OHTA's guidelines emphasize the value of controlled clinical trials, few evaluations have had the benefit of such rigorous evidence (352).

Like its predecessor NCHCT, OHTA provides recommendations to HCFA about the appropriateness of providing Medicare coverage for a technology which it has assessed. OHTA does not release its assessment until HCFA has taken action on the recommendation. The assessments, but not the recommendations, are published and disseminated.

The formation of the Prospective Payment Assessment Commission (ProPAC), mandated with the passage of the Social Security Amendments of 1983 (Public Law 98-21), initiates a new Government involvement in medical technology assessment for payment purposes. ProPAC members were appointed in November 1983, and the body's activities started in the early part of 1984. ProPAC is an independent advisory committee that is empowered to collect and assess information on hospital costs and productivity, technological advances, and the cost effectiveness of hospital services. It is required to use existing information where possible but is also given authority to carry out research and to award grants and contracts. ProPAC will make recommendations to the Secretary of DHHS concerning the appropriate payment rate under Medicare's DRG payment system for inpatient hospital services. ProPAC also has broad powers to assess medical technology and the appropriateness of medical practice patterns.

Private Sector Activities

In the private sector, the Blue Cross and Blue Shield (BC/BS) associations often rely on evaluations of medical technology in arriving at coverage and reimbursement decisions. Like Medicare, the BC/BS associations make a majority of coverage decisions through a decentralized and loosely structured process that places key emphasis on two criteria used in Medicare's coverage policy: stage of development and acceptance by the medical community.

Some BC/BS member plans use informal methods to evaluate medical technologies. The medical advisors of individual plans may make coverage determinations based on immediate personal knowledge or may survey the literature and consult with advocates of the procedure, local specialty societies, the county medical society, and other area insurers. If the plan functions as a contractor for Medicare, as an agent for Medicaid, or as an agent for the armed services CHAMPUS program, the medical advisor will generally review the coverage determinations of these programs. Similarly, the medical advisor will usually study the coverage recommendations of the national BC/BS Association and other member plans, although he or she may not follow any previous rulings (353).

On the other hand, there are BC/BS plans that follow an extremely formal procedure for assessment. A particularly active State affiliate, Blue Shield of California, established a Medical Policy Committee in 1966 to assess the scope and limits of Blue Shield's standard medical insurance policies with respect to new diagnostic and therapeutic procedures (52). This committee has continued its interest in evaluating technologies in the interest of cost containment.

Blue Shield of Massachusetts is actively involved in technology assessment, as well. A separate committee, the Interspecialty Medical Advisory Committee, is incorporated into its decisionmaking structure. One of the advisory committee's main duties is to make recommendations concerning medical, surgical, or therapeutic procedures, i.e., to determine the "general acceptability" of a new service or procedure. Only those services or procedures deemed "generally accepted" by Blue Shield are reimbursed. The "generally accepted" guidelines promulgated by Blue Shield of Massachusetts are very similar to those used by OHTA in performing its assessments for coverage purposes (see ch. 5). According to the Blue Shield guidelines (41):

> . . . a generally accepted surgical or medical procedure is a procedure which:
>
> a) has completed the research or experimental stage of development;
>
> b) does not involve, as an integral part of the procedure, the use of any drug, substance or device which has not been released by the Food and Drug Administration or other governmental licensing agencies for general use by qualified physicians;
>
> c) is in general use for patient care by physicians qualified to perform the procedure;
>
> d) is of demonstrated value for the diagnosis or treatment of an illness, injury, or bodily function.

There are very specific definitions and clarifications for the administration of the Massachusetts Blue Shield guidelines, including a requirement for factual material such as the rates of mortality and morbidity associated with the technology. A health care provider (or group of providers) contacts his or her specialty society committee concerning coverage of a new technology. There are 30 such committees. The specialty society committee then assesses the surgical or medical procedure according to the guidelines just described. If the new technology is approved, the recommendation with all necessary supporting information is presented to Blue Shield's Interspecialty Medical Advisory Committee, which then decides on a fair reimbursement level for the service/procedure. After going through additional steps in the organizational structure, the recommendation is formalized. If coverage is denied, there is opportunity for a request for reconsideration.

The assessment performed by Blue Shield of Massachusetts differs from that performed by OHTA in a number of ways. One important way is that attention is paid in the Blue Shield evaluation to other established procedures that are equal to the procedure under consideration in merit or effectiveness as well as in their morbidity and relative cost. Another important consideration in performing a Blue Shield evaluation is the cost of the prosthesis/device/drug/substance which is an integral part of the proposed procedure.

The coverage recommendations of the national BC/BS Association are made using two mechanisms: the Medical Advisory Subcommittee and the Medical Necessity Program. The Medical Advisory Subcommittee, composed of six medical directors from individual affiliates, meets four times a year to make coverage decisions. Requests for coverage determinations may originate either directly from a manufacturer or provider or indirectly from one of the local plans. After the national BC/BS staff conducts research on the product or service, which may include collecting the opinions of professional medical associations, the Medical Advisory Subcommittee either reaches a coverage decision or postpones a decision until further information on the product or service is available for review (141).

Cost considerations are more likely to be explicitly included in the evaluation of a technology by the Medical Advisory Subcommittee than they are in evaluations for Medicare. During the initial review for the Medical Advisory Subcommittee, the BC/BS staff gathers information about the reimbursement level for the product or services, or similar product or services, where possible. Furthermore, when a decision is reached, it is reviewed by the Providers Affairs and Cost Containment Review Committees and then by the National Blue Cross and Blue Shield Board Review. The coverage determinations, which go out as a recommendation to the 106 local U.S. BC/BS plans, usually concern new technology and are expressed in broad terms. However, sometimes they specify indications for use.

The Medical Necessity Program was developed in 1977 in conjunction with the American College of Physicians (ACP), the American College of Surgeons (ACS), and the American College of Radiology. It was designed to curtail reimbursement for obsolete, duplicated, and outmoded procedures (41). In 1977, the Medical Necessity Program advised BC/BS plans to discontinue routine payment for a group of 42 procedures unless physicians provided special medical justification for their use. Since 1977, the original list of 42 procedures has been expanded to nearly 100 (41). In 1979, on the basis of the recommendations of ACP and ACS, the Medical Necessity Program advised BC/BS plans to pay for diagnostic tests performed at the time of admission to hospitals only when the tests had been specifically ordered by a physician.

The stated objectives of the Medical Necessity Program—cost containment and the improvement of quality of care—remain the same as in 1977. The focus of the program, though, was expanded in 1980 from evaluating possibly obsolete procedures to examining procedures that may be overutilized or inappropriately utilized. In October 1982, the BC/BS national associations recommended new guidelines to member plans "intended to raise the level of cost consciousness" about the unnecessary use of certain respiratory care procedures, with expectations of potential savings of hundreds of millions of dollars annually (326).

In arriving at its recommendations, the Medical Necessity Program draws on the advice of national medical specialty organizations including ACP. Indeed, ACP's involvement in evaluating the safety, efficacy, and effectiveness of clinical tests, procedures, and therapies began with its participation in the project (230).

Commercial insurance companies make independent coverage decisions regarding the coverage of new and emerging technologies. When a coverage question arises, a company may contact the Health Insurance Association of America (HIAA). HIAA is a trade association of 338 commercial insurance companies. It will provide information to its member companies on the medical appropriateness of diagnostic and therapeutic procedures. HIAA does not conduct technology assessments, but reports opinions rendered by the Council of Medical Specialty Societies (CMSS) through its program for clinical procedure review (193). In late 1977, CMSS agreed to accept questions from insurers with HIAA acting as the intermediary between the many insurance companies and CMSS. HIAA will transmit the information to the requesting insurer and publish the CMSS opinion in its "Medical Relations" bulletin. Each company makes its own coverage policy decision using its discretion.

Some prepaid group practices have also had experience with medical technology assessment. The Department of Medical Methods Research of the Kaiser-Permanente Medical Care Program (KPMCP) of Northern California has conducted research on the utilization of modern technology for the development of improved methods of providing and delivering medical care within the KPMCP (72). The primary purpose of the department's Division of Technology Assessment is to aid in the selection of the most cost-effective technology. The process of assessment the division uses is quite different from that employed elsewhere, primarily because of the unique financial structure of prepaid group practices. In a prepaid group practice, an increase in the use of a technology often increases expenses and does not generate revenues as it might in fee-for-service or cost-reimbursement programs. In addition, there are no savings from the purchases of equipment that could increase cash flow. Thus, the incentives are for low-cost technology that maintains or improves the effectiveness of medical care.

Assessments at the KPMCP begin with the identification of a technology that uses substantial resources. Next, the characteristics of the population utilizing the technology and the workloads for its utilization are determined. Alternative technologies used for the same specified objectives are evaluated as to important intended and unintended consequences. The technology assessments use epidemiological methods, controlled studies, medical record studies, literature reviews, consensus development, and sensitivity analyses. The results of the assessments are presented as important consequences of alternative technologies so that management can make more rational decisions.

A number of medical specialty societies are interested in technology assessment. ACP is now conducting the Clinical Efficacy Assessment Project (CEAP), a major effort to study the efficacy, clinical effectiveness, and safety of tests, procedures, and therapeutic interventions. CEAP evaluated 50 procedures and tests from January 1981 through November 1983 and as of March 1984 had 11 other evaluations in process. Almost all the technologies that have been evaluated to date were submitted by the Federal Government or insurance companies who generally use the result in their coverage and reimbursement decisions (21).

The steps in ACP's evaluation process are similar to those used by OHTA. CEAP draws on its membership for information on the technology under evaluation, and after developing a draft statement, sends the statement to outside experts for review. The final statement is written by staff with the help of ACP's Clinical Efficacy Subcommittee.

In addition to ACP, other medical specialty societies and medical associations have either initiated or intensified existing activities involved with medical technology assessment during the past few years. Among these are the American College of Cardiology (ACC), the American Medical Association (AMA), and the American Hospital Association (AHA).[3] Although the assessment activities of these organizations are not as directly linked with coverage and reimbursement decisions as ACP's have been, their findings are often used by public and private insurers.

ACC has three activities related to technology assessment. First, it responds to requests from Federal agencies as well as from the private sector (e.g., hospitals, clinics, third-party carriers) about the standards, criteria, and appropriateness of procedures usually performed in a hospital setting by physicians treating cardiovascular diseases. Second, it has a Joint Task Force in conjunction with the American Heart Association that undertakes in-depth technology assessments. The assessments include criteria of contribution uniqueness, sensitivity, specificity, indications and contraindications, and cost effectiveness.

The third activity of ACC is new and under development. A Cardiovascular Norms Committee is being formed, to "establish and obtain consensus on dynamic norms (defined as factors essential for quality care decisionmaking) for the diagnoses and management of the most common cardiac diagnoses, including cost effectiveness of alternate plans or diagnostic techniques." The first step of this ambitious undertaking is to investigate a mechanism for developing dynamic norms (a type of criteria setting) (196).

AMA has been involved in evaluating and providing information of technologies through its scientific publications; through a series of reports published by its Council of Scientific Affairs dealing with diagnostic, therapeutic, and other medical technologies; and by responding to thousands of inquiries that involve information on assessment of medical technologies, particularly those that are well established. AMA just began a new project, Diagnostic and Therapeutic Technology Assessment (DATTA), whose purpose is to "expeditiously and effectively examine medical technologies that are passing from experimental or investigational to accepted forms of treatment and define, where possible, indication for their use." It is intended that the assessments will be limited to the evaluation of the safety and effectiveness of a technology (196).

Other private sector parties with a longstanding involvement in medical technology assessment, especially to determine safety and efficacy, are manufacturers of drugs and devices. They initiate research and are required by FDA to conduct tests for premarket approval of their products. Large private clinics, e.g., the Cleveland and Mayo Clinics, also perform some assessments[4] (359).

Recently, AHA and other members of the hospital community have become actively involved in evaluating technologies, but mainly from the perspective of planning for new health care services and in reviewing existing services. AHA has played a catalytic role in this authority by issuing the manual, *Technology Evaluation and Acquisition Methods for Hospitals (TEAM)*, in 1979 (13). The program described in the manual not only provides a mechanism for hospitals to evaluate technologies for financial reasons but also emphasizes evaluation with respect to community needs and hospitals' role in the community.

AHA has continued to involve its members in recent developments in technology and technology assessment through its Hospital Technology Series Guidelines Reports, published as part of the Hospital Technology Series, which are individual reports devoted mainly to specific technologies. They usually examine the key factors a hospital should include when evaluating a particular technology for purchase, as well as product information on commercially available models of the technology.

In addition, hospitals and hospital chains, such as Humana and the Hospital Corporation of America, are examining technologies more carefully than before. However, when they evaluate technology, it is most often with respect to an "overall risk management program for the identification, evaluation, and treatment of risk or financial loss" (292). The Hospital Corporation of America, for example, recommends the formation of a Product Selection Committee by each of its member hospitals. The committee's purpose is to evaluate the degree of inherent risk to each patient and/or employee posed by material that may be introduced into or is already being used within the hospital (171). Prepaid group practices, such as Kaiser-Permanente of Northern California, conduct technology assessments in order to improve their methods of providing and delivering medical care within their organization.

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[3] The American Academy of Pediatrics, the American Public Health Association, the American College of Radiology are among the other professional associations used that have taken part in evaluating technologies. Their activities are discussed in the OTA report *Strategies for Medical Technology Assessment* (359).

[4] See *Strategies for Medical Technology Assessment* for a description of their activities (359).

Finally, ECRI (formerly the Emergency Care Research Institute) is a nonprofit organization primarily involved in comparative product evaluations of diagnostic and therapeutic devices and hospital equipment and supplies. ECRI provides a type of "consumer report" service for hospital administrators that gives ratings to comparable medical technologies based on performance safety, ease of use, and cost effectiveness. An emphasis on the larger economic, social and ethical issues surrounding health care technologies has recently been added. Further, ECRI maintains a computerized health devices data base on over 6,000 categories of devices and hospital equipment (28).

Public/Private Sector Activities

There are some indications of cooperation between the public and private sector and among members of the private sector in evaluating medical technologies. Massachusetts Blue Shield, for example, has been sending its Interspecialty Medical Advisory Committee's monthly agenda to HCFA's Office of Coverage Policy for 2 years (436). This mechanism informs the Office of Coverage Policy of current issues pertaining to technology assessments considered in Massachusetts by Massachusetts Blue Shield's Interspecialty Medicare Advisory Committee. The monthly agendas are also exchanged with the Blue Shield of New Jersey's Medical Advisory Committee and with the National Blue Cross and Blue Shield Medical Advisory Committee and their staff. Furthermore, the national BC/BS Association has begun a comprehensive medical policy manual that will be the basis for a uniform medical policy for all of the Blues nationwide (436).

The activities just mentioned are but a few of the numerous efforts underway to evaluate medical technologies. The proliferation of medical technologies and the absence of an organization to coordinate and complement existing technology assessment activities prompted the Institute of Medicine (IOM) to appoint a committee to develop a plan for a technology assessment organization that would be based in the private sector and supported by both governmental and nongovernmental funds (234). The IOM report recommended the establishment of a medical technology consortium that would function under the auspices of IOM during an initial period of development, and then, after approximately 5 years, function as an independent entity in the private sector. The functions of the medical technology consortium would be as follows:

- to serve as a clearinghouse of information on medical technologies and medical technology assessment;
- to assemble and evaluate information and make recommendations concerning individual medical technologies;
- to act when necessary and appropriate to stimulate, coordinate, undertake, or commission medical technology assessments, including activities that would complement those of others;
- to identify needs in the assessment of specific medical technologies;
- to develop and evaluate assessment criteria and methods; and
- to provide education, training, and technical assistance in the use of medical technology assessment methods and results.

The IOM report noted that the "consortium is not intended as a competitor or replacement for an existing entity involved in assessing medical technologies." Rather, it is to be complementary and facilitative of the efforts of others involved in responsible assessments of medical technologies. The report recommended that when the consortium first starts to function, initial emphasis should be placed on the clearinghouse function because of expected financial constraints. A proposal for the creation of the consortium awaits funding (169).

Appendix D.—Selected Alternatives to Traditional Health Care Delivery

Introduction

Strategies for containing Medicare costs by changing the incentives for the adoption and use of medical technology were identified in chapters 5 through 8. Chapter 8 identified examples of alternatives to traditional health care delivery sites and organizations[1] that might stimulate competitive behavior by health care providers. The purpose of this appendix is to provide additional information on those alternatives. Available data on utilization by Medicare patients and costs to the program of these alternatives have been included in this appendix to illustrate potential data and evaluation needs. Assuming that a current goal of the Medicare program is to contain or reduce costs without compromising quality of care, it is reasonable to examine alternative sites and organizations of health care delivery for their potential in helping attain that goal.

Development of Alternative Sites and Organizations for Health Care Delivery

The precise reasons for the creation of alternative sites and organizations for health care delivery are difficult, if not impossible, to specify, although the causes of the proliferation of alternative sites and organizations for health care delivery clearly include economic and social forces. As the prices of medical care have soared, coverage of services by public programs such as Medicare and Medicaid and expanded coverage of services by private insurance companies have enabled a greater number of persons to obtain needed health services (135). Entrepreneurs responsive to financial incentives throughout the health care system have joined physicians and other health care providers in developing alternative sites and organizations of health care delivery. Many of the alternatives have developed as for-profit operations (325), and they have fostered competition in local markets. Freestanding ambulatory surgery centers and health maintenance organizations (HMOs), for example, developed under the influence of specific market conditions (e.g., overscheduled hospital operating rooms in the case of the centers and increased supply of physicians and Federal encouragement in the case of HMOs). Other alternatives have been developed to provide services at more convenient times and in more convenient locations for patients. Emergency care centers are an example.

Medicare itself has had varying impacts on the establishment of alternatives. Home health care agencies have proliferated since Medicare began covering home visits in 1966. Ambulatory surgery centers, on the other hand, developed without Medicare coverage, and although freestanding centers have received specific coverage since September 1982, the impact of the new coverage is unknown. Emergency care centers generally do not encourage Medicare patients to use them, and some even exclude Medicare patients except in life-threatening situations. The Medicare program was used to directly encourage the development of HMOs.

A major question with respect to alternative sites and organizations of health care delivery is whether the alternatives are less costly to patients, to the Medicare program, or to both. Some alternative sites (e.g., ambulatory surgery centers) may substitute for traditional hospital and physician office sites for some patients, while others (e.g., emergency care centers) may complement them. Covered sites of care may or may not save money, depending on the extent and appropriateness of use. As long as lower cost health services are *substituted* for more expensive ones, Medicare will save. If instead, the alternatives are used *in addition* to more expensive, traditional care, Medicare costs will rise. Potential cost savings for the Medicare program depend on the number of beneficiaries using any service, on the prices paid for medical technologies in various sites, and on the quality of the care produced. Quality is important in its own right. It is also important in economic terms, though, because lack of it may cost the beneficiaries and the program more in the long run.

Measurements of quality of care for alternative sites are controversial. For those sites of care and services specifically covered by Medicare, there are conditions of participation that providers must meet in order to receive payment. The conditions for freestanding ambulatory surgery centers, for example, specify that such centers must meet State licensing requirements and obtain accreditation by an appropriate association. Medicare conditions of participation have been criticized for concentrating on the structure and process aspects of quality measures (176) instead of on patient outcomes. In home health care, the Medicare conditions of participation have been important in developing quality assurance programs (176).

Costs of alternative sites for health care delivery are not easily compared. There are no published studies that account for differences in case mix and services rendered by freestanding emergency care centers, hospital emergency rooms or outpatient departments, or physicians' offices (2,325). One study on ambulatory care found slight differences in case mix between hospital outpatient departments and private physician office practices (200). Measuring differences in costs of various sites is also difficult, because hospitals, for example, do not use consistent methods of reporting costs, and, thus, do not accurately measure the true cost of ambulatory care (2). Measuring utilization of the alternative sites also presents problems. The customary measure is the visit, but differences in case mix, use of tests and procedures, and standby equipment and staff are not adequately accounted for by the visit measure (2).

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[1] Prominent examples of "traditional" sites or organizations are the independent community hospital, the solo, fee-for-service physician, and use of only hospitals for surgery.

The incentives for provider behavior will be changed by Medicare's new prospective per case payment system for inpatient hospital services (see ch. 6). Under the payment system based on Diagnosis Related Groups (DRGs), hospitals have financial incentives to decrease lengths of stay and substitute outpatient services for inpatient services. Increased use of outpatient visits might help prevent use of inpatient care, but the research evidence is mixed (33). Early discharges of hospitalized patients will probably increase the need for care in skilled nursing facilities (SNFs) and for home health care. Hospice care may also be affected by the DRG payment system, although in the absence of previous Medicare experience with hospices, interpretation of the evidence will be difficult.

The discussion below provides information on selected alternatives to traditional health care delivery. The first section discusses alternative sites of care, i.e., alternatives to inpatient care in hospitals and to primary care in physicians' offices. The second section describes two alternative organizations for health care delivery, HMOs and preferred provider organizations (PPOs), both of which may increase competition in the health field.

Alternative Sites of Health Care Delivery

Patients can obtain different types of medical care in a variety of locations. The sites described here are alternatives to inpatient care in hospitals and to primary care in physicians' offices. The discussion of each alternative site includes patterns of use, evidence on cost and quality of care, and effects of Medicare policy. Unfortunately, data vary in availability and quality, so comparisons are not always possible.

Alternatives to Inpatient Hospital Care

Entrepreneurs have reacted to the availability of money in the health care system by providing alternative sites for hospital care. In some cases, medical technologies are being moved from their traditional sites in hospitals to other locations. Certain surgical procedures have been moved from traditional hospital sites to ambulatory surgery centers. Hospital inpatient care for acute illness is being complemented, and, in some cases, replaced by home health and nursing home care. Palliative care for terminally ill patients has also been moved out of hospitals to hospices. These alternatives are described below.

Ambulatory Surgery Centers.—Units to accommodate ambulatory surgery were developed in the early 1970's in response to overcrowded operating room schedules and inconvenience to patients and physicians (125). Ambulatory surgery centers could not have been established without the technological improvement of fast-acting anesthesia and the practice of making patients walk soon after surgery (125). Some units are affiliated with hospitals and are located either in the hospitals or at other sites. Other units are not associated with hospitals. These units, known as freestanding ambulatory surgery centers, are often physician-owned. Surgical procedures that are appropriate to ambulatory surgery centers are those using general anesthesia but requiring only a few hours of postoperative monitoring of the patient. Patients are carefully screened. In recent years, third-party payers have accepted claims for surgery performed in these centers, and some now require that certain procedures be done on an ambulatory basis for coverage.

On September 7, 1982, Medicare changed its coverage of ambulatory surgery to encourage more patients and surgeons to use the less expensive freestanding ambulatory surgery centers (108). The purpose was to increase substitution of ambulatory surgery for inpatient surgery. The utilization of ambulatory surgery centers since that change is unknown. Yet there was sufficient concern about the possibility of adding to the surgical rate for Medicare beneficiaries that the General Accounting Office was requested to study utilization patterns in the first year of the new coverage policy (177).

Prior to the policy change, there was diversity in the age distribution of patients among freestanding ambulatory surgery centers, but there is no single source of reliable aggregate numbers of ambulatory surgical procedures *by age group* (325). From 1973 to 1980, surgical rates rose even more rapidly for the elderly than for the general population in the United States (5). In 1967, 85.4 per 1,000 Medicare beneficiaries had surgery during their hospitalizations; but in 1972, the rate was 93.4; and in 1976, it was 104.9 surgeries per 1,000 beneficiaries (162). Again, improvements in anesthesia and in some procedures have reduced the risks of some types of surgery. More surgery is required, also, as people age and suffer from cataracts, cancer, and cardiovascular diseases.

Freestanding ambulatory surgery centers generally charge less than hospital inpatient or hospital outpatient surgery for most procedures. Clearly, inpatient surgery is more expensive, because patients must pay for a hospital stay of at least 1 day. In addition, freestanding ambulatory centers can charge lower prices because their construction costs are lower, they do not need some of the most expensive technologies available in hospital operating rooms, and their overhead is lower since many of the hospital ancillary services (e.g., food services) are not needed (124,428). It is likely that these fixed costs of the hospital setting will be spread among fewer surgical procedures, which will result in higher costs for hospital surgery.

Under Medicare, freestanding ambulatory surgery facility costs are covered for 100 specific procedures (an additional list of 50 has been proposed) in four groups to encourage use of the centers. Facility fees are prospectively set by the Health Care Financing Administration (HCFA), and the schedule is based on complexity of procedure with no beneficiary deductible or copayment. The least complex and least costly procedures (e.g., gastroscopy) are in Group 1, for which Medicare pays the center $231; the most complex and costly ambulatory surgical procedures (e.g., laparoscopy) are in Group 4, for which facilities are paid $336 (108). Physicians who accept assignment are paid 100 percent of reasonable charges for covered services. By statute, Medicare expenditures for ambulatory surgery must be less than they would be if the procedures were performed on an inpatient basis. HCFA estimated that this benefit would save $2 million for Medicare in its first year of operation.

Since hospital outpatient surgery is usually reimbursed 80 percent of costs with a 20-percent copayment, some hospitals with ambulatory surgery units might be at a disadvantage with regard to Medicare payment unless they elect to participate as though their units are freestanding ambulatory surgery centers, i.e., accept the prospective fee schedule rather than cost-based reimbursement. To participate as freestanding units, they must establish centers that are physically, administratively, and financially independent from the rest of the hospital (108).

Quality of care in ambulatory surgery centers appears to be good. The centers have reported no deaths and lower complication rates than inpatient surgery (29,82,248). There is an accreditation association to advance their credibility to the public. In addition, centers that want to participate in Medicare must meet Medicare conditions of participation requiring that certain staff and equipment be available.

Home Health Care.—Continued growth in the home health industry is expected in response to the incentives under Medicare's DRG hospital payment system for shorter inpatient stays. The number of agencies providing home health care services has greatly increased since 1966 when Medicare began covering skilled nursing care and physical and speech therapy to homebound elderly people. The purposes of providing those services was to lower the hospital length of stay for acutely ill patients, thus cutting costs to the program.

The specific aspects of home health care have changed over time. Currently, the basic services are part-time or intermittent nursing care by or under the supervision of a registered nurse; physical, occupational, or speech therapy; medical social services; and part-time or intermittent services from a home health aide. Certain medical technologies that used to be administered only on an inpatient basis (e.g., intravenous antibiotic therapy) are now part of home health care (248).

Home health agencies may be licensed by the States, although the licensing requirement for Medicare participation was eliminated in 1980 with the passage of the Omnibus Reconciliation Act (Public Law 96-499) (207). Visiting nurses associations were among the first home health agencies (223). Other home health care providers are public health departments, hospitals, and independent agencies, both for-profit and not-for-profit. The hospital-affiliated home health agencies alone almost doubled between 1979 and 1982, when they numbered 450 and more than 720 respectively (207).

The number of home health care visits paid for by Medicare almost tripled between 1969 and 1980 (from 8.5 million to 22.4 million) (392). Studies of home health care in the 1970's seemed to indicate that home care made early discharges from hospitals possible. Recent studies looked at overall hospital use, but not readmission rates or length of stay (333), so the long-term effect of the early discharges and substitution of home care is not evident.

Home health care as a substitute for an extended hospital stay may be underutilized, although it appears to be used more often than SNFs by Medicare patients

(391). In 1980, home health agency services were used by 890,400 elderly and 67,000 disabled Medicare beneficiaries. Medicare reimbursed the agencies providing these services a total of $662.1 million (392). A General Accounting Office study of home health care demonstration projects showed mixed effects of expanded home health care on Medicare costs (333). Several demonstration projects have studied the effects of expanded home health care on patient outcomes: their results are also mixed (333).

The Omnibus Reconciliation Act of 1980 (Public Law 96-499) changed Medicare's home health care coverage by eliminating the remaining copayments, the limit on number of visits, and the hospitalization requirement. Patients must be homebound, under the care of a physician, and in need of skilled nursing or physical or speech therapy. Medicare Part A covers all home health visits unless a beneficiary has Part B coverage only. In the latter case, Part B covers the home health services (391).

Nursing Homes.—SNF care usually consists of skilled nursing care and rehabilitation services. Medicare covers 100 days of care in an SNF following an acute episode of illness. There is a required daily copayment of one-eighth of the Part A deductible ($44.50 in 1984) for days 20 through 100 in an SNF.

Not all SNFs are participants in Medicare. This situation exists in part because there is some financial risk posed by submitting claims to Medicare intermediaries that may deny payment, and in part because Medicare patients may require more intensive nursing care than the longer term chronically ill Medicaid and private-pay patients (106). Because there is limited access to SNF beds, Medicare patients have often remained in the hospital for extra days. For these patients, Medicare has paid as much as four times the necessary cost of patient care, possibly totaling $100 million to $900 million extra annually (106). By encouraging earlier discharges from hospitals, the DRG payment system will probably decrease these backup hospital days, estimated at from 1 million to 9.2 million annually (104). To alleviate the SNF bed shortage, some hospitals with extra beds are converting them into nursing home beds for long-term care (103, 320). Hospital reporting requirements for skilled nursing beds are different from the reporting requirements for separate SNFs, so this bed conversion may not reduce costs to Medicare (278).

In 1980, 269,500 elderly and 9,300 disabled Medicare enrollees used SNF days (161). Yet Medicare pays only 2 percent of the total SNF industry revenues. In 1980, Medicare paid $339.3 million to SNFs for elderly beneficiaries and $13.5 million for disabled beneficiaries who were admitted. Table D-1 shows that discharges from and days of care in SNFs by Medicare enrollees have declined since 1969 (391), when a rigorous claims review policy resulted in retroactive denial of many claims and substantial loss of revenues for some SNFs (106).

Quality of care in nursing homes is variable. The Joint Commission on Accreditation of Hospitals accredits nursing homes. Medicare conditions of participation for SNFs are complex. State licensure requirements of nursing homes often have different definitions of "skilled" and "intermediate" care facilities than does HCFA. In many cases, nursing homes choose not to

Table D-1.—Use of and Reimbursement for Skilled Nursing Facilities (SNFs) Under Medicare by Type of Enrollee, 1969-79

	Discharges (thousands)		Days of care (thousands)		Reimbursements (millions)	
Year	Elderly	Disabled[a b]	Elderly	Disabled[b]	Elderly	Disabled[b]
1969	367.9	NA[c]	14,467.0	NA	$277.3	NA
1970	277.4	NA	9,901.0	NA	200.3	NA
1971	237.8	NA	7,230.0	NA	164.7	NA
1972	218.0	NA	5,837.0	NA,	140.8	NA
1973	237.2	2.2	6,372.0	51.0	157.7	$ 1.5
1974	262.8	8.0	7,185.0	216.0	197.4	6.7
1975	252.1	8.2	6,618.0	222.0	195.6	7.6
1976	255.6	8.7	6,808.0	232.0	219.4	8.6
1977	260.8	8.9	7,145.0	249.0	243.8	9.8
1979	269.6[d]	9.6	7,821.0	297.0	306.1	12.9
Annual compound rate of growth (%)	−4.2	3.6[e]	−8.4	4.9[e]	−1.6	13.5[e]

[a] Includes SNF discharges with at least 1 day of covered care under Medicare. Excludes stays for enrollees who had exhausted their SNF benefits and for whom no discharge record was received.

[b] Preliminary estimates.

[c] NA—Not applicable.

[d] Represents Medicare beneficiaries admitted rather than those discharged.

[e] Annual compound rate of growth computed only for 1974-77 because the 1973 figure does not cover a full year due to a change in eligibility policy, and the 1979 data represent slightly different information and thus are not included in the calculation.

SOURCE: C. Helbing, "Medicare: Use of Skilled Nursing Facilities, 1976-77," *Health Care Financing Notes*, U.S. DHHS publication No. 03021 (Baltimore, Md.: Health Care Financing Administration, 1980).

participate in Medicare because of the extra administrative burden of multiple regulations and requirements.

Hospices.—The hospice is a relatively new concept in care for patients with terminal illnesses. Until hospice care became available in this country, beginning in 1971, most terminally ill patients had been kept in hospitals and nursing homes. Terminally ill patients have usually undergone highly sophisticated treatments (e.g., radiation therapy, chemotherapy, and extensive surgery) without success. In hospices, such patients receive palliation of their symptoms and psychosocial care from a multidisciplinary team that includes physicians, nurses, social workers, clergy, psychologists and psychiatrists, dieticians, lawyers, and specially trained volunteers. Home care is one of the desirable aspects of hospice, for economic as well as psychological reasons, although it is not always possible. Furthermore, the use of many volunteers by hospices helps keep costs low. There are about 500 full-service and 500 part-service operating hospices and 80 in the planning stages (362). In 1982, Congress mandated in the Tax Equity and Fiscal Responsibility Act (Public Law 97-248) that Medicare cover 6 months of hospice care for terminally ill Medicare eligibles under Part A.

There is no experience to report on hospice use by Medicare beneficiaries, because hospice care is a new benefit. However, during congressional deliberations, the Congressional Budget Office estimated that potential users would number 268,000 in fiscal year 1984 but only about 12,000 would use the benefit that year (257).

Prices for hospice care have been based on the type of care and on costs from demonstration project hospices. The type of care is determined by how much nursing time a patient requires in a day. Costs differ between freestanding hospice units and hospital-based units. Medicare will pay a maximum of $6,500 per patient per year, on an aggregate basis (112).

Alternatives to Physicians' Offices

Primary medical care traditionally has been provided in physicians' offices. In recent years, however, alternative sites of primary care have been established in response to economic, social, and health factors. The supply of physicians has increased in many regions, so there is competition for patients. In addition, Medicare and Medicaid, among other Government programs, have provided funds for medical care for the elderly and the poor, thereby increasing the potential patient population. Patients' expectations have increased, and the U.S. population itself is growing older and needs more medical care. Two examples of alternative sites of primary care, hospital outpatient clinics and emergency care centers, are described below. Emergency care centers are also alternative sites for outpatient care.

Hospital Outpatient Departments.—Hospitals, particularly teaching hospitals, have long had outpatient departments. Yet in recent years, one of the ways hospitals have responded to financial pressures has been to expand services, including primary care in outpatient departments (136). The increased use of hospital ambulatory care in recent years is also due to limited access to private physicians for inner-city residents, increasing prevalence of chronic diseases, and greater expectations of patients for medical care from hospitals (2). Advances in medical technology have also resulted in the movement of some treatments from inpatient to outpatient settings (136,157,248). Visits to hospital outpatient departments by the elderly have been increasing, while the rest of the population has been using fewer outpatient visits (210).

Some hospitals are also establishing satellite clinics, i.e., decentralized sites where ambulatory care is available (142). Primary care clinics have been set up by many community hospitals throughout the country (40). Specialized clinics for the outpatient treatment of cancer patients have also been opened in some urban areas (263).

Over 10 percent of the physician visits made by persons 65 and older in 1978 were visits to hospital outpatient departments or emergency rooms (210). This was a 22.2-percent growth in outpatient department visits since 1973 for that age group. About one-third of these outpatient visits were to the emergency room, one-third to a physician in a clinic, and one-third to ancillary service referrals (210). The growth, especially in the ancillary service referrals and clinic visits, will probably continue after the implementation of Medicare's DRG payment system.

Hospital outpatient department and emergency room visits are combined in Medicare Part B statistics. In 1980, Medicare reimbursed $1.9 billion for outpatient services for about 7.5 million beneficiaries (392).

Medicare Part B pays 80 percent of reasonable charges for visits to hospital outpatient departments and emergency rooms. Part B beneficiaries must pay the initial deductible ($75 since 1983) and 20 percent coinsurance, just as they do for a physician office visit. Reasonable charges differ between physician offices and hospitals, and for outpatient visits, hospital charges are generally higher. Because hospitals must accept Medicare assignment, however, some patients may have an incentive to use hospital outpatient services instead of physician office visits.

Emergency Care Centers.—Emergency care centers are alternatives to hospital outpatient departments and to some emergency room care and to primary care in physician offices. Such centers, though generally equipped with some emergency technologies, do not treat life- or limb-threatening situations, so the name "emergency" may be misleading (325). They usually have more diagnostic technologies on location than a physician's office. Emergency care specialists and some family practitioners have opened emergency care centers to make medical care more accessible to patients who have no primary care physician or who cannot find a physician after hours. The centers have extended hours during evenings and weekends when physicians' offices are closed, and some are open 24 hours a day, 7 days a week. No appointments are necessary, so care is more convenient for some patients, although patients may not experience desired continuity of care.

Use of emergency care centers by the elderly has not been well documented. While one estimate of total visits to these centers was 12 million patient visits for 1982 (238), the elderly population is probably underrepresented. To keep costs down, most freestanding emergency care centers accept cash or credit cards only (325), so patients must be reimbursed by their insurance companies. This requirement may deter elderly and disabled patients with limited incomes from using the centers. Furthermore, most freestanding centers do not accept Medicare assignment, and this means more money out-of-pocket for elderly and disabled beneficiaries.

Emergency care centers usually compare their charges with those of hospital emergency rooms rather than with fees for physician office visits. This comparison is not necessarily a good one, because the care provided is often more like office than hospital care. Nonetheless, the National Association of Freestanding Emergency Centers estimates that center charges are 30 to 50 percent lower than hospital emergency rooms for comparable services (238). If an emergency care center is affiliated with a hospital, Medicare will reimburse for visits as though the center were a hospital department. If the center is freestanding, Medicare will pay as though the visit were a physician office visit (55). Hospitals must accept assignment to participate in Medicare, but physicians and freestanding centers need not. Thus, if elderly patients were informed about which centers were hospital affiliated or accepted assignment, they would be more likely to choose those centers over the other centers if total prices were comparable. A 1979 study showed that most of the emergency care centers' revenues came from private insurers or patients who paid directly, with only a small fraction coming from Medicaid and even less from Medicare beneficiaries (55). The 1983 followup, although limited in sample size, showed more centers accepting Medicare funds but some centers specifically excluding Medicare cases (250).

The National Association of Freestanding Emergency Centers has a policy of not judging the quality of care delivered in individual facilities but leaving that judgment to the patients (238). The centers are characterized as physician offices for quality review purposes by the physicians practicing in them. There are no licensing laws for freestanding emergency care centers in most States, although some States are trying to regulate them (239). If Medicare were to develop a special benefit program for emergency care centers like that for ambulatory surgery centers, more evidence of quality would probably be required in the conditions of participation.

Alternative Organizations for Health Care Delivery

Organizational differences among health care providers allow patients choices and increase competition in the health care market. This section describes two examples of alternative organizations that may increase competition among providers. Patterns of use, evidence on cost and quality of care, and effects of Medicare policy are presented for HMOs. PPOs are described only briefly because of a lack of information.

Health Maintenance Organizations

A defined set of physicians who provide services for a voluntarily enrolled population paying a prospective per capita amount is known as a group practice prepayment plan (GPPP). Some GPPPs have accepted financial risk for hospitalization of their patients and have become part of the competitive health care market known as HMOs. These organizations, thus, are both providers and insurers of comprehensive but specified medical services.

In a series of laws, the Federal Government has provided financial support for HMO development, including construction loans and mandatory access for HMOs (i.e., employers must offer an HMO health plan as an option for health insurance coverage). Not all HMOs have participated in these Federal programs because of the regulations imposed on participating HMOs (227). From 5.3 million enrollees and 142 plans in 1974, HMO enrollment doubled to 11.6 million enrollees in 269 plans in 1982 (85). Still, HMOs cover only about 5 percent of the U.S. population.

The growth of HMOs and other GPPPs since the early 1970's has not been accompanied by a similar growth in the number of Medicare enrollees joining these groups. By March 1982, 45 HMOs had cost contracts, 2 had normal risk contracts, and 8 had special experimental demonstration risk contracts with Medicare (392). Another 33 GPPPs were also participating under Medicare in less restrictive contracts (392). Just under 116,000 HMO members were Medicare enrollees as of March 1982, and about 515,000 Medicare enrollees were GPPP members (392). Thus, around 2 percent of the Medicare population is participating in an HMO or GPPP.

Under the Social Security Amendments of 1972 (Public Law 92-603), payment to HMOs for Medicare beneficiaries could be made under the usual cost-based method or under a risk-sharing contract. Most HMOs with Medicare enrollees are under a cost-contracting arrangement with Medicare in which they receive monthly interim payments based on their estimated allowed costs with a year-end adjustment to allowed costs (392).

As of March 1982, only two HMOs were under a risk contract in which its adjustment was compared with the adjusted average per capita cost (AAPCC) for its services. The AAPCC is the average per capita cost of providing services to the enrolled group of beneficiaries if they had been receiving fee-for-service care in their area (there are more specific actuarial and demographic factors that are used in calculating the actual AAPCC). If the HMO's costs are lower, it retains half of the savings above 80 percent of the AAPCC, for a maximum of 10 percent. Higher costs must be absorbed or carried over into the next budget year (392).

In September 1982, HCFA began funding five demonstration projects on a risk contract basis to see if significant numbers of Medicare beneficiaries could be enrolled in HMOs through aggressive marketing techniques and attractive benefit packages (97). These demonstrations have added significance in view of prospective payment provisions in the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248), and the establishment of Medicare's prospective hospital payment system using DRGs in the Social Security Amendments of 1983 (Public Law 98-21). One reason why HMOs have not actively sought to enroll Medicare beneficiaries may be that HMOs operate on a per capita payment basis, while their participation in Medicare necessitated significant administrative costs in order to conform to Medicare requirements for cost-based data. Medicare prospective payment would be in tune with HMO operations, and HMOs can be expected to be more aggressive in seeking Medicare beneficiaries. Another consideration in increasing HMO participation in Medicare is that beneficiaries need incentives to join HMOs, because many would have to change physicians and hospitals and would have less freedom of choice of physicians and hospitals in HMOs (145).

Analyses of Medicare beneficiaries' use patterns prior to their enrollment in three of the HCFA HMO demonstrations addressed the issue of whether beneficiaries sicker than the average Medicare enrollee would be attracted to HMOs or whether HMOs would recruit Medicare beneficiaries who had fewer medical problems on average (i.e., whether adverse or favorable selection from the standpoint of the HMO would occur) (97).

In two of the HMOs, which were closed-panel HMOs, pre-enrollment use rates of Medicare-reimbursed services were lower than the use rates of comparison group beneficiaries. In the third HMO, which operated much like an independent practice association (IPA) and which was the only significant provider of care in the area, there was no difference between the enrolled and comparison groups. The analysts studying the HMOs concluded that the circumstances under which enrollment occurred probably ruled out deliberate selection of healthier beneficiaries by the closed-panel HMOs and that the selection bias was probably on the part of the enrollees. As beneficiaries enrolling in the closed-panel HMOs probably had to give up their previous doctors and hospitals, these two HMOs may have enrolled Medicare beneficiaries who did not have close ties to their physicians. In the IPA-type HMO, most enrollees were probably receiving care from a physician who belonged to the IPA and therefore did not have to change physicians (97).

Interim results a study of one of the closed-panel HMOs (Oregon Region Kaiser-Permanente Medical Care Program) have shown that Medicare beneficiaries can be motivated to join HMOs through premium savings or increased benefits over those available from the fee-for-service sector and that there is a high level of acceptance of continued HMO participation (145). In regards to utilization, recruited Medicare members used hospital beds at a rate slightly higher than individuals over 65 previously enrolled in the plan. But the recruited Medicare members' rate of use was still much lower than the rate of all individuals over 65 in the same area—1,677 days per 1,000 members per year versus 3,142 days per 1,000 people per year. New members also used about 20 percent more office visits than old members of the same age group. The successful recruitment of additional members and increased utilization of services through the enhanced Medicare coverage provided in the demonstration projects led the authors to hypothesize the following: 1) prior Medicare coverage did not meet a significant amount of need, and/or 2) those selecting HMOs were more likely to use services. These interim results also support the conclusion reached earlier in the preenrollment study (97) that the HMO did not recruit healthier beneficiaries.

The evidence on cost savings by HMOs centers around lower hospital utilization, although there is some evidence that physicians in HMOs use fewer tests and procedures than physicians paid on a fee-for-service basis (203). One of the reasons HMOs have not enrolled more Medicare patients may be that the aged and disabled require more costly care, including more physician visits and more hospitalizations, than a younger, healthier population.

Numerous studies have examined the structure, process, and outcome factors of quality for HMOs (205). In addition to the difficulty of defining and measuring quality, comparisons of HMO practices to fee-for-service practices are complicated by the insurance aspects of the former which change the financial incentives. The evidence on quality in HMOs does not support the contention that HMOs save money by providing lower quality care (204). Neither does the evidence support the suggestion of substantially better care in all HMOs (205). Thus, care in HMOs appears to be about equal in quality to that received through fee-for-service practices under conventional insurance coverage (429).

Preferred Provider Organizations

PPOs include a variety of organizational designs. Basically, PPOs are contract agreements between an insurer (or employer, if self-insured) and providers (physicians or hospitals or both) that give services at a reduced rate to the insured group. Patients are given a choice of seeing a physician from the PPO list at little or no out-of-pocket cost or seeing someone else and having to pay the difference in fees.

Incentives for the insurers to enter into PPO agreements include reduced cost because of the reduced rate and some control over utilization of medical technologies. This control comes from an agreement by the physicians to participate in utilization review and quality assurance programs. Physicians who overutilize tests and procedures potentially will be dropped from the PPO list. There are also incentives for physicians to agree to the discounts of 5 to 20 percent (191). First, insurance claims on a fee-for-service basis will be paid quickly and in full. Second, billing is easier for these patients. Finally, patient volume is guaranteed to be increased. Indeed, most PPOs have been initiated in areas where there are a very large number of physicians.

It is difficult to determine the number of PPOs because PPOs are agreements among entities, not entities themselves. Concentrations of PPOs are in Denver, Los Angeles, and San Francisco (100). MediCal (California's Medicaid program) is contracting with California hospitals, and a new law in that State allows contracting between hospitals and other third-party payers. Blue Cross and Blue Shield of Virginia is trying to set up a PPO in the Richmond area (147). Blue Cross and Blue Shield of Michigan is developing a PPO for Medicare recipients in Detroit under a HCFA grant (59). Data are not available on patient participation rates in PPOs. The agreements are too new to have generated much publishable data, and they are too diverse to use their data in comparisons with other physician organizations.

It is still too early to draw conclusions regarding cost and quality of PPOs. If patients choose the physicians offering reduced fees, the third-party payers may save. At the same time, these physicians have agreed to participate in utilization review and quality assurance programs. The design and implementation of these programs will be important to their acceptance by physicians and to their effectiveness.

Discussion

As noted earlier in this report, the original purpose of the Medicare program was to increase the access to medical care for the Nation's elderly population. Currently, the primary focus of policymakers is on cost containment. This appendix has described examples of alternative sites and organizations for health care delivery. These alternatives may represent future directions for Medicare cost-containment efforts.

Rational encouragement of the best alternatives would benefit the Medicare program and its enrollees. In order to decide which alternatives would provide the best quality of care at a low cost, comparisons of evidence on costs and quality are needed. This appendix has presented available evidence on patterns of Medicare beneficiaries' use of several alternatives and the available evidence on cost and quality. Clearly, more research and better data collection are needed. Definitional problems regarding quality, cost, and what constitutes a particular type of care exacerbate the paucity of comparable data (2,205,429).

Appendix E.—Decisionmaking by Medicare Contractors for Coverage of Medical Technologies

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Introduction

This study of decisionmaking by Medicare contractors was conducted for OTA to determine whether there is variation in decisionmaking by Medicare contractors (intermediaries and carriers) with respect to the coverage of particular medical technologies.The findings are based primarily on the results of a 1983 telephone survey of Medicare contractors.

Background and Objectives

Conventional wisdom holds that there is wide variation in the decisions made by Medicare contractors regarding the coverage of particular medical technologies. This variation stems from the absence of precise national policy about which medical care technologies are "reasonable and necessary" and, hence, eligible for reimbursement; the decentralized process by which Medicare coverage policy is promulgated and implemented; and the wide range of discretion allowed to individual contractors in making coverage and reimbursement decisions (54,143,353). Variation in Medicare contractors' interpretation of rules governing coverage of skilled nursing care has been documented (314). However, comparable information is not available to document the variation in contractors' coverage decisions about medical technologies.

Any attempt to change the economic incentives in the Medicare program by refining coverage policy in order to control or modify the adoption and use of medical technology, thereby constraining the growth of Medicare costs, ideally would be grounded on a better understanding of the way in which coverage decisions are currently made. This study was intended to assist in developing that information base by addressing the following specific objectives:

1. To determine the manner in which Medicare intermediaries and carriers identify new technologies and new uses of established technologies;
2. To determine the manner in which intermediaries and carriers monitor and implement national coverage decisions; and
3. To determine whether there is variation among intermediaries and carriers in Medicare coverage of specific technologies:
    - a. by any type of technology (drugs, devices, and medical and surgical procedures); and
    - b. by stage of development (experimental, new, and established).

This appendix presents the study findings. It includes a discussion of study methods, a description of findings with respect to reported coverage policies and factors associated with those policies, and a summary of conclusions.

Methods

The study requirements included drawing a sample of Medicare carriers and intermediaries, selecting the technologies for which specific coverage questions were formulated, developing and pretesting the questionnaire, and gathering and analyzing the survey data. The various aspects of the study methodology are presented in the following sections, along with a discussion of study limitations.

Sampling Plan

The sampling plan was developed to reflect characteristics of Medicare contractors that were hypothesized to influence their coverage decisionmaking. Adequate representation of both commercial insurance companies and Blue Cross/Blue Shield (BC/BS) plans was indicated because of the possibility that variation in claims processing between these groups might influence coverage decisions. Discussions with staff of OTA, the Health Care Financing Administration (HCFA), local BC/BS plans, and nearby hospitals suggested that intermediaries are more limited than carriers in their ability to identify new technologies or new uses of established technologies because of the restricted information provided by the hospital claim form. Accordingly, both carriers and intermediaries were represented. The potential variation in physician practice patterns among geographic regions required a geographically balanced sample. To simplify the analysis, we preferred to avoid disproportionate sampling from fractions among these groupings of contractors. In the absence of firm information about the likely variation in decisionmaking among contractors, the sample size was governed primarily by the need to balance the contractors' characteristics specified above and the time and funds available for conducting the study. A total sample size of 60 contractors was deemed reasonable.

After determining the target sample size, the most recent HCFA intermediary and carrier directory was used as the sampling frame (385). Contractors in Hawaii and Puerto Rico were eliminated because of the time and expense involved in communicating with them. The HCFA Offices of Direct Reimbursement and Group Health Operations were also eliminated. (These offices serve as intermediaries and carriers for providers who bill HCFA directly, and, as such, have a unique national perspective. Because of pending organizational changes, however, information about their operations would provide little useful data on which to make policy recommendations.)

Random sampling resulted in an initial sample of 21 intermediaries and 39 carriers, whose distribution among Blue Cross/Blue Shield and commercial insurance contractors and geographic region is shown in table E-1. After telephoning to verify the names and addresses of persons in charge of government programs, a letter of introduction was sent to each sampled contractor, which described the purpose of the study and indicated that the program administrator would be contacted to schedule an interview.

Almost immediately, however, changes were required in the initial sample. Both the verification phone calls prior to mailing the introductory letter revealed that in many cases the HCFA directory was outdated. Some contractors no longer held HCFA contracts but were able to tell us who the current contractor was. In these instances, we replaced the prior contractor with the current contractor in order to maintain the geographic representativeness of the sample. Two other categories of sampled contractors performed no claims review functions: Railroad Retirement Boards, who contracted for review with a commercial insurance company; and home offices of large commercial companies, whose review functions were performed by field offices. Both were listed in the HCFA directory and given intermediary or carrier numbers, so there was no way to identify them in advance. When such contractors were identified, they were declared ineligible for inclusion in the sample because they were not engaged in claims review. They were subsequently replaced by another randomly selected contractor.

The final sample of contractors is shown in table E-2, which reflects the changes discussed above. Four contractors (all Blue Cross or Blue Shield plans) refused to participate. Their reasons for nonparticipation reflected extreme staff shortages and time pressures involved in the need to implement system changes demanded by the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) and Social Security Amendments of 1983 (Public Law 98-21). Despite these changes, the representation of carriers and intermediaries remained about the same in both the original and final samples. Similarly, the distribution of contractors among HCFA regions remained about the same except that the minimum representation decreased in the final sample (i.e., only three contractors in the Denver region).

Questionnaire Development

A telephone-administered questionnaire was developed to elicit information about intermediaries' and

Table E-1.—Distribution of Initially Sampled Medicare Contractors

	Number of carriers		Number of intermediaries		
HCFA region	BC/BS	Commercial	BC/BS	Commercial	Total
Seattle	1	2	2	1	6
San Francisco	1	2	1	2	6
Denver	2	2	0	0	4
Dallas	2	2	1	0	5
Kansas City	3	2	1	1	7
Chicago	2	3	3	0	8
Atlanta	3	2	1	1	7
Philadelphia	2	0	2	0	4
New York	2	3	1	1	7
Boston	1	2	1	2	6
Total	19	20	13	8	60

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

Table E-2.—Distribution of Actual Study Participants

	Number of carriers		Number of intermediaries		
HCFA region	BC/BS	Commercial	BC/BS	Commercial	Total
Seattle	1	2	1	1	5
San Francisco	1	2	1	2	6
Denver	2	1	0	0	3
Dallas	2	2	1	0	5
Kansas City	3	2	1	1	7
Chicago	2	2	3	0	8
Atlanta	3	4	1	0	8
Philadelphia	3	0	2	0	5
New York	1	1	1	2	5
Boston	2	1	2	0	5
Total	20	17	13	6	56

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

carriers' claims review processes, their uses and impressions of HCFA transmittals that update the Medicare coverage issues appendix, their methods for identifying technologies for which coverage may be questionable, and their policies with respect to covering certain technologies specified in the questionnaire. Potential questionnaire items were discussed with regional and national reimbursement experts. Two pilot tests were conducted, and additional questions were eliminated or refined in order to accommodate the 40-minute time limit.

The most complicated aspect of questionnaire development was identifying the technologies about which coverage questions were asked. This task was handled primarily by the physician member of the study team, in consultation with colleagues at the University of Iowa College of Medicine, medical consultants in insurance companies, and staff of OTA, HCFA, and the Office of Health Technology Assessment (OHTA) of the Public Health Service (PHS). In addition, recent HCFA updates to the coverage issues appendix, the Commerce Clearinghouse version of the appendix, and lists of studies completed or underway by OHTA were carefully reviewed.

As indicated by the study objectives, the technologies about which coverage questions were asked were chosen to represent a variety of types (drugs, devices, and medical and surgical procedures) at various stages of development (experimental, new, and established). This diversity was intended to raise different coverage issues reflecting questions about the extent to which these technologies are safe, effective, and generally accepted within the medical community. Developing a matrix of technologies for potential inclusion in the study proved to be difficult, however, since assigning individual technologies to these categories frequently required some arbitrary decisions. The dividing points between experimental, new, and established technologies are not clear-cut. Determining whether a procedure is medical or surgical may reflect personal biases about which medical specialty should be permitted to perform it, as well as its contribution to diagnostic v. therapeutic decisions, and its relative degree of invasiveness. The questionnaire was designed to include some technologies for which there is an explicit HCFA policy and some for which there is not, in which case Medicare contractors are expected to make their own determinations. Finally, Medicare coverage policy is constantly evolving. Even during this limited study period, there were changes in HCFA policy and its interpretation. The technologies included in the questionnaire are shown in table E-3. However, the sometimes arbitrary and fluid nature of the manner in which they are categorized should be noted.

Data Gathering

The interviews were conducted by a nonphysician senior member of the study team and two research assistants who were second-year graduate students in hospital and health administration. All interviewers consulted with the physician member of the study team and reviewed medical literature and the coverage issues appendix in order to become thoroughly familiar with the nature and uses of the medical technologies included in the study. Our intent was to interview a senior official from each Medicare contractor, who would be familiar with the overall processes by which claims were reviewed, as well as the contractor's specific coverage policies. In most cases, the respondent was a nonphysician administrator responsible for the Part A or Part B Medicare contract. Sometimes, physician consultants and nurse reviewers responded; occasionally, a conference call was held so that all three

Table E-3.—Medical Technologies Included in Questionnaire

Technology	Type of technology	HCFA policy	Developmental stage	Use[b]
Intraocular lens implant following cataract removal	Surgical procedure	Covered	Experimental/new	Therapeutic
Chelation therapy with EDTA in the treatment of atherosclerosis	Drug/medical procedure	Not covered	Experimental	Therapeutic
Chelation therapy with EDTA in the treatment of rheumatic arthritis	Drug/medical procedure	Local option	Experimental	Therapeutic
Pacemaker device and its implantation for a patient with chronic second degree AV block of Mobitz type II, with symptoms attributable to intermittent complete heart block	Device/surgical procedure	Covered[a]	Established	Therapeutic
Pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms	Device/surgical procedure	Covered[a]	Established	Therapeutic
Implantable chemotherapy infusion device, such as the "Infusaid," and its implantation for a patient with primary hepatic malignancy, such as hepatoma	Device/surgical procedure	Covered[a]	New	Therapeutic
Implantable chemotherapy infusion device for a patient with metastatic cancer in the liver	Device/surgical procedure	Covered[a]	New	Therapeutic
External insulin infusion pump for a diabetic patient	Device	Covered[a]	Experimental/new	Therapeutic
Purchase of a home blood glucose monitor such as the Dextrometer®	Device	Covered[a]	Established	Diagnostic
Continuous 24-hour monitoring of blood pressure using an automatic device (i.e., preset intervals not under control of patient for readings)	Device/medical procedure (interpretation)	Not covered (as of July 1983)	New	Diagnostic
Continuous 24-hour monitoring of blood pressure using a semiautomatic or patient-activated device	Device/medical procedure (interpretation)	Not covered	New	Diagnostic
Percutaneous transluminal coronary angioplasty (PTCA) for a single vessel procedure	Medical procedure	Covered[a]	New/established	Therapeutic
PTCA for two or more coronary arteries	Medical procedure	Not covered[a]	New	Therapeutic
Streptokinase administration at cardiac catheterization into a coronary artery to dissolve a clot in a patient with acute myocardial infarction (thrombolytic therapy)	Drug/medical procedure	Local option	Experimental	Therapeutic
External osteogenic stimulator for use in the treatment of a long bone fracture	Device/medical procedure	Covered[a]	New	Therapeutic
Chemonucleolysis (i.e., injection of the enzyme chymopapain or "Discase") in the treatment of a herniated disc	Drug/medical or surgical procedure	Local option	Experimental/new	Therapeutic
Electroencephalographic (EEG) monitoring during carotid endarterectomy	Medical procedure	Covered[a]	New use of established	Diagnostic
EEG monitoring during open heart surgery	Medical procedure	Not covered	New use of established	Diagnostic
Apheresis (therapeutic pheresis) or plasma exchange in the treatment of hyperglobulinemias such as a multiple myeloma	Medical procedure	Covered[a]	New or new use of established	Therapeutic

Table E-3.—Categorization of Medical Technologies Included in Questionnaire—Continued

Technology	Type of technology	HCFA policy	Developmental stage	Use[b]
Apheresis (therapeutic pheresis) or plasma exchange in the treatment of systemic lupus erythymatosis (SLE)	Medical procedure	Not covered	Experimental use of established	Therapeutic
Topical oxygen therapy for decubitus ulcers (e.g., Topox device)	Device/medical procedure	Not covered	Experimental	Therapeutic
Biofeedback therapy for intractable pain	Device/medical procedure	Not covered	New use of established	Therapeutic
PUVA therapy for psoriasis	Device/medical procedure	Covered[a]	New	Therapeutic

[a] Indicates that Medicare coverage is contingent on compliance with specified criteria or guidelines.
[b] "Diagnostic" includes use to monitor or guide therapy.

SOURCE: L. K. Demio, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

perspectives could be represented. The latter occurred at the suggestion of the respondent. The variation in respondents introduces the potential for bias; however, when the data were analyzed according to the position and discipline of the respondent, no systematic differences were detected.

Another source of potential bias was introduced by variation in the method by which answers were obtained. As noted earlier, the questionnaire was designed to be administered by telephone. In some instances, however, the respondent insisted on reviewing the questionnaire in advance and then responding by telephone or submitting the answers by mail. This occurred when the respondents were short of staff or when the contractor had a policy of only responding to self-administered mail questionnaires. Rather than lose the respondent, we reluctantly agreed to send the questionnaire in advance. Finally, in some cases, respondents were unable to respond to all the questions about technologies and preferred to check on coverage policy and provide the answers later, either in a followup telephone call or in writing.

Obviously, the respondents who reviewed the questionnaire in advance or who provided answers in followup contacts had the opportunity to consult the coverage issues appendix and provide the "correct" answer. We attempted to minimize this possibility in several ways. In administering the questionnaire, we were careful to emphasize that we expected variation to occur, that there was no "correct" answer, and that we were simply interested in ascertaining what the contractor's customary policy would be. In some instances, there was a general HCFA coverage policy, but in others, there was not. Ultimately, the data were analyzed according to the method by which answers were obtained; entirely by telephone interview (61 percent of the responding contractors); entirely by self-administration (14 percent); or by a combination of telephone interview and followup telephone or written response to questions that were initially unanswered (25 percent).

When the reported coverage policies for individual technologies were categorized according to these three general methods of response, a statistically significant difference was found for only one technology (the implantation of a pacemaker for a patient with sinus bradycardia without symptoms). For this technology, the responses derived entirely through a telephone interview indicated lowest adherence to HCFA policy, while those based on mixed methods showed highest adherence. The differences in reported coverage for a 24-hour, semiautomatic or patient-activated blood pressure monitor were almost statistically significant ($p = 0.079$). In this case, the responses to questions that were totally self-administered showed lowest adherence to HCFA policy, while those based on mixed methods again showed highest adherence. For all other technologies for which HCFA has established a coverage policy, the differences were not statistically significant at the 0.05 level and were about evenly divided among general methods of response. However, there remained a slight tendency (not statistically significant) for responses from contractors who utilized the combination method or self-administered responses to show greater adherence to HCFA policy. If one assumes that the responses derived entirely from telephone interviews are most likely to reflect actual contractor behavior (e.g., the reviewer simply made a decision based on the claim without bothering to refer to the coverage issues appendix), then the findings from this study are biased in the direction of underestimating deviation from HCFA coverage policy.

Study Limitations

The potential for bias stemming from the sample, variation in the position and discipline of the respondent, and the methods by which responses were obtained was noted above. In addition, responses reflect the opinion of (usually) one respondent at one point in time about a limited set of medical technologies. Thus, the data would not reflect potentially different judgments about coverage policy made by different individuals within a single contractor organization or by a single individual at different points in time. Time and resource limitations precluded an indepth survey of all contractors in a manner that would illuminate both inter- and intracontractor variability in coverage decisions, categorized by a wide range of technologies and administrative and policy variables. Perhaps a more definitive study would be based on the submission of actual, identical claims to a sample of Medicare contractors and the analysis of variation in claims processing and decisionmaking; however, that was not our charge.

Despite the limitations of the current study, we believe that the findings are generally reliable and that the resulting information on coverage decisions of a sample of Medicare contractors should provide a useful framework for considering alternative Medicare coverage policies.

Findings

Although there was variation in reported coverage decisions by the Medicare carriers and intermediaries in our study, the processes by which claims are reviewed were quite predictable. The characteristics of the participating contractors are described below.

Characteristics of Participating Contractors

The 56 Medicare contractors (37 carriers and 19 intermediaries) included in the study reported fairly similar methods for processing Medicare claims. After an initial review of completeness, most claims pass through (potentially) three levels of review that reflect differing degrees of comprehensiveness, specificity, and clinical judgment and involve clerical employees, registered nurses, and physicians or some other health professional (pharmacist, podiatrist, occupational therapist, etc.) in that order. All but nine (16 percent) of the respondents utilized some automated screening procedures that vary in sophistication. The nine respondents without automated screening procedures were all intermediaries (contractors that process Part A claims), rather than carriers (contractors that process Part B claims). The most common computerized screens flag cases that exceed certain utilization parameters (specified numbers of hospital days, office visits, lab services, nursing home visits, etc.), claims requesting payment for noncovered services, incompatible diagnostic and procedure codes, and claims involving diagnoses, procedures, or providers which are automatically submitted to medical review by physicians.

The referral of claims to registered nurses is generally based on rather clear-cut screening and referral guidelines, recorded in policy manuals and employed either by clerical workers or automated review processes. All but two contractors (4 percent) also have established criteria to assist nurse reviewers in determining when to refer a coverage question to a medical consultant. Referral guidelines often reflect cases that have been troublesome in the past, as well as claims for technologies for which there is no prior claims experience, so there is no precedent for making a coverage determination. Some guidelines specify particular conditions or technologies for which review by a physician consultant is always required, such as bypass surgery, pacemaker implantations, computed tomography (CT) scans, and cases involving enteral and parenteral feeding.

Physician consultants utilize their own knowledge of medical practice and the scientific literature to resolve many coverage questions. Institutional sources of information utilized by consultants in making coverage determinations are shown in table E-4. The HCFA regional office, colleagues in other insurance companies or BC/BS Plans, and State and national medical and specialty associations are most frequently consulted. Professional Standards Review Organizations (PSROs) (now utilization and quality control peer review organizations (PROs)) are least frequently used. Other resources include "inhouse" peer review panels, publications of the Food and Drug Administration (FDA), drug manuals, informal medical consultation, and policies established for private programs whose claims are also processed by the Medicare contractor. The responses were very similar for both commercial insurance companies and BC/BS plans, except that the "Blues" were much more likely to turn to national insurance associations (in this case, the Blue Cross and Blue Shield Association), while commercial insurers were more likely to rely on State or national medical or specialty associations. The responses for intermediaries and carriers were also quite similar, except that intermediaries were more likely than carriers to rely on information from PSROs, HCFA regional offices, national insurance associations, and manufacturers. These differences were not statistically significant, however.

Most contractors report that they learn about new technologies for which coverage questions might be raised prior to the actual submission of claims through inquiries from providers and manufacturers, drug and

Table E-4.—Sources of Information Used by Medical Consultants in Making Coverage Decisions

Sources	Percent of consultants using source	
	Yes	No
Colleagues in another insurance company or BC/BS plan	78.6	21.4
HCFA regional office	87.5	12.5
University medical center	44.6	55.4
PSRO (PRO)	26.9	73.1
National insurance association	37.5	62.5
State or national medical or specialty association	75.0	25.0
Drug or device manufacturer	53.6	46.4
Other	51.0	49.0

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

device approval lists from the FDA, and HCFA announcements. Once claims are submitted, new technologies are identified because of the absence of code numbers or the presence of codes that are not recognized by the claims reviewers. A few contractors conduct extensive research to assist in identifying and making coverage decisions for such claims, utilizing in-house review panels, specialists in nearby medical colleges, and medical journals. The majority, however, assume a more passive role. Similarly, the majority are reasonably well satisfied with existing methods for identifying new technologies and report that this is not a big problem for them. Some mentioned a need for greater cooperation between national medical and insurance associations and governmental agencies, as well as faster turnaround on coverage decisions, once questions are raised. There were no noticeable differences between intermediaries and contractors in these responses.

The volume of claims processed by the study contractors varies widely. During the March to January quarter of 1983, the total number of Medicare claims processed ranged from 18,000 to 4,155,000 claims per contractor, with a mean of 854,741.

Reported Coverage Decisions

The basic data reflecting reported coverage decisions for specified medical technologies are shown in table E-5. The columns headed "covered" and "not covered" include clear-cut responses with no associated qualifications or criteria. To estimate the frequency with which contractors cover individual technologies, the reader should combine the responses from the first and third columns. The latter include responses indicating that coverage would be dependent on compliance with specified criteria or guidelines, discussed in more detail below. Whenever possible, respondents were limited to these first three categories, even if that required a followup phone call to determine actual coverage policy. The fourth, fifth, and sixth columns (referral to the coverage issues appendix, to a physician consultant, or to the HCFA regional office) may be viewed as "last resort" responses. They were used in instances where the respondent had never heard of the technology, or had never seen a relevant claim, and had no precedent for making a decision other than to refer to one of the three sources of assistance. The number of responses is sometimes less than the total number of study participants. Since the same questions were asked of both carriers and intermediaries, there were some instances when the question was not applicable. For intermediaries, this was especially true for questions about durable medical equipment for home use. When a question was not applicable, the response was coded as "missing data" and excluded from the reported responses.

Table E-5 reveals some instances of near unanimity or high levels of agreement in coverage decisions—particularly for intraocular lens implant following cataract removal (98.2 percent covered), the use of chelation therapy in the treatment of atherosclerosis (87.0 percent not covered), and the use of topical oxygen therapy for decubitus ulcers (86.3 percent not covered). However, there are also examples of considerable variation in coverage policies—particularly for a pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms, an implantable chemotherapy infusion device for a patient with metastatic liver cancer, an external insulin infusion pump for a diabetic patient, and streptokinase administration at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction. These responses and their implications are perhaps better presented in table E-6, which categorizes them according to HCFA coverage policy.

Table E-5.—Reported Coverage Decisions for Specified Medical Technologies

Technology	Covered	Not covered	Covered with qualifications	Referral to coverage issues appendix	Referral to physician consultant	Referral to HCFA regional office	Number of responses
Intraocular lens implant	98.2%	—	—	1.8%	—	—	55
Chelation therapy: atherosclerosis	—	87.0%	3.7%	7.4	1.9%	—	54
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	7.5	1.9	3.8%	53
Pacemaker: chronic second degree AV block	70.9	—	20.0	1.8	7.3	—	55
Pacemaker: sinus bradycardia without symptoms	13.0	44.4	29.6	1.9	11.1	—	54
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	3.8	11.5	—	52
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	3.8	13.5	1.9	52
External insulin infusion pump	10.6	46.8	27.7	4.3	8.5	2.1	47
Home blood glucose monitor	11.8	7.8	72.5	7.8	—	—	51
24-hour blood pressure monitoring: automatic	8.3	52.1	27.1	4.2	6.3	2.1	48
24-hour blood pressure monitoring: semi-automatic or patient-activated	4.2	77.1	8.3	6.3	4.2	—	48
PTCA: single vessel procedure	61.1	3.7	25.9	9.3	—	—	54
PTCA: 2 or more coronary arteries	19.2	51.9	19.2	3.8	3.8	1.9	52
Streptokinase at cardiac catheterization:	30.2	45.3	15.1	1.9	5.7	1.9	53
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8	—	—	51
Chemonucleolysis: herniated disc	64.0	10.0	14.0	2.0	8.0	2.0	50
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	6.0	2.0	—	50
EEG monitoring: open heart surgery	15.4	71.2	9.6	1.9	1.9	—	52
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7	—	—	53
Apheresis: systemic lupus erythymatosis	18.0	60.0	14.0	4.0	4.0	—	50
Topical oxygen therapy: decubitus ulcers	7.8	86.3	5.9	—	—	—	51
Biofeedback: intractable pain	9.3	55.6	31.5	1.9	1.9	—	54
PUVA: psoriasis	38.5	5.8	50.0	—	1.9	3.8	52

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

Technologies Covered by HCFA

The technologies for which HCFA explicitly provide coverage[1] have a higher percent of responses indicating unqualified coverage than those in any subsequent coverage category (see table E-6). The implantation of an intraocular lens provides an exception to HCFA's general policy of not covering experimental or investigational items or services. Although FDA still considers intraocular lenses to be investigational, Congress directed FDA to study them without interfering with their availability to patients. Lens implantation is the only technology included in this study for which almost all respondents (about 98 percent) indicated a policy of unqualified coverage. For the remaining technologies in this category, most qualified responses reflect the contractor's policy of assuring that HCFA's coverage criteria are met, even though the questions were phrased so as to leave little doubt about their eligibility for coverage. Because of the publicity surrounding pacemakers, many contractors automatically submit all such claims to medical consultants for indepth investigation prior to payment. If the qualified and unqualified coverages are combined, close to 90 percent of the respondents indicated that they approve coverage for the technologies that are explicitly covered according to HCFA policy. The one exception was electroencephalographic monitoring during carotid endarterectomy, which reportedly would not be covered by about 14 percent of the contractors.

Table E-6.—Reported Coverage Decisions by Medicare Contractors

	Decisions/policy of contractors			
Technology/HCFA coverage policy	Covered	Not covered	Covered with qualifications	Refer for advice
HCFA explicitly covers:				
Intraocular lens implant	98.2%	—	—	1.8%
Pacemaker: chronic second degree AV block	70.9	—	20.0%	9.1
PTCA: single vessel procedure	61.1	3.7%	25.9	9.3
EEG monitoring: carotid endarterectomy	68.0	14.0	10.0	8.0
Apheresis: hyperglobulinemias (multiple myeloma)	81.1	5.7	7.5	5.7
HFCA covers with qualifications:				
Home blood glucose monitor	11.8	7.8	72.5	7.8
External osteogenic stimulator: long bone fracture	27.5	3.9	58.8	9.8
PUVA: psoriasis	38.5	5.8	50.0	5.8
Implantable chemotherapy infusion device: primary hepatic malignancy	51.9	21.2	11.5	15.4
Implantable chemotherapy infusion device: cancer metastatic to liver	38.5	26.9	15.4	19.2
External insulin infusion pump	10.6	46.8	27.7	14.9
No explicit HCFA policy—contractor decides (local option):				
Chelation therapy: rheumatoid arthritis	3.8	81.1	1.9	13.2
Streptokinase at cardiac catheterization: AMI	30.2	45.3	15.1	9.4
Chemonucleolysis: herniated disc	64.0	10.0	14.0	12.0
HCFA denies, but not explicitly:				
Biofeedback: intractable pain	9.3	55.6	31.5	3.7
PTCA: two or more coronary arteries	19.2	51.9	19.2	9.6
Apheresis: systemic lupus erythymatosis	18.0	60.0	14.0	8.0
HCFA explicitly denies:				
Chelation therapy: atherosclerosis	—	87.0	3.7	9.3
Pacemaker: sinus bradycardia without symptoms	13.0	44.0	29.6	13.0
24-hour blood pressure monitoring: automatic policy effective 7/83)	8.3	52.1	27.1	12.5
24-hour blood pressure monitoring: semiautomatic or patient activated	4.2	77.1	8.3	10.4
EEG monitoring: open heart surgery	15.4	71.2	9.6	3.8
Topical oxygen therapy: decubitus ulcers	7.8	86.3	5.9	—

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

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[1] One may argue that even for these technologies, HCFA specifies some criteria or guidelines for approving coverage. For example, the services must still be reasonable and necessary for the individual patient. With respect to pacemakers, HCFA has specified three groups of medical indications that: 1) may be covered without further claims development, 2) require more specific claims information, or 3) would generally result in denial. Furthermore, final coverage determination of a claim for pacemaker implantation must "take account of the circumstances of the particular claim, as well as factors such as the medical history of the individual patient." However, our phrasing of the questions in the first grouping was such that their eligibility for Medicare coverage was intended to be obvious.

The second category of technologies in table E-6 includes those for which HCFA has delineated criteria that must be met in order for coverage to be approved and for which our descriptions of the procedure were less specific than in the first category. The qualifications associated with approving a claim for the purchase of a home blood glucose monitor, the use of an external osteogenic stimulator in the treatment of a long bone fracture, and the use of PUVA for psoriasis consistently reflect the application of criteria specified in the coverage issues appendix. If the qualified and unqualified coverages are combined, from 84 to 88 percent of the respondents approve coverage for these three procedures, although some approvals may be granted without ascertaining whether the specified criteria are met.

The responses pertaining to the coverage of infusion devices require somewhat more interpretation. Currently, the only pertinent national coverage instructions are those in section 60-9 of the coverage issues appendix and in section 2100.5 of the Medicare carrier's manual. The coverage issues appendix provides that infusion pumps are covered if the contractor's medical staff verifies the appropriateness of the therapy and of the prescribed pump for home use. The Medicare carriers manual provides that reimbursement may be made for supplies necessary for the effective use of durable medical equipment, citing as an example tumor chemotherapy agents used with an infusion pump, as long as the drug or biological used with a pump is reasonable and necessary for the patient's treatment. The state of the art of infusion pump technology has changed considerably since these policies were developed. They have been interpreted by HCFA to include an implantable pump such as that manufactured by the Infusaid Corp. (referred to in the questionnaire), even though the policies were not developed with that technology in mind. PHS is examining issues related to the coverage of infusion pumps, including chemotherapy and insulin devices. HCFA is postponing the issuance of revised chemotherapy guidelines until those studies are completed. The responses to our questionnaire items reflect this uncertainty.

The respondents were most likely to cover an implantable chemotherapy infusion device, such as the "Infusaid," and its implantation for patients with primary hepatic malignancy, such as hepatoma. They were less likely to cover the same device for a patient with cancer metastatic to the liver. They were least likely to cover an external insulin infusion pump for a diabetic patient; of the three technologies, the responses cover the total range of response options—perhaps more so than for any other technology considered to this point. The circumstances of coverage for the chemotherapy infusion device reflected FDA approval status of the drug to be administered, as well as the condition of the patient. For example, one respondent indicated that the device would be covered for a patient with metastasized liver cancer only if the liver were the key to survival and at least a 6-month survival period were likely. Criteria were also specified for coverage of an external insulin infusion pump, including patient condition (e.g., a "brittle diabetic"), case-by-case review to assure medical necessity rather than simply convenience, and a multidisciplinary assessment of diet and exercise programs and patient motivation. One respondent indicated that the same criteria would be applied as for a home blood glucose monitor.

"Local Option" Technologies

Technologies are included in the coverage issues appendix only if they have presented difficult coverage questions for Medicare contractors, who generally would have submitted them to a HCFA regional office, and, eventually, to the central office in Baltimore for a national coverage determination. HCFA policy holds that individual Medicare contractors should make coverage decisions for all technologies that are not mentioned in the coverage issues appendix. In other words, their coverage status is determined by "local option."[2] The technologies included in this study that fall into the "local option" category all involve the use of drugs, which in turn, requires that contractors refer to FDA policy in making Medicare coverage decisions. These technologies are included in the third category in table E-6.

Although the drug mentioned in our questions about chelation therapy (endrate or disodium EDTA) has been approved by FDA, the labeling indications do not mention its use for rheumatoid arthritis. About 81 percent of the respondents approve coverage of streptokinase administered at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction, as well as chemonucleolysis injections in the treatment of a herniated disc. In both instances, coverage is generally contingent on FDA approval. The timing of the streptokinase is important: respondents require that it be administered from 4 to 6 hours after onset of symptoms; one respondent required that the patient be placed in a specialized care unit postoperatively. In approving chemonucleolysis claims, two respondents require that its use be limited to the lumbar region; two others require that the provider have special training.

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[2] This distinction between technologies for which coverage is specified in the coverage issues appendix and those for which coverage is expected to be a matter of local option is overly simplistic and glosses over an important source of ambiguity and confusion in HCFA policy. Not all technologies that are not mentioned in the coverage issues appendix are expected to be a matter of local option. As discussed in the next section, some technologies are not explicitly denied in the coverage issues appendix, even though, according to HCFA staff, the contractors should know that they are not covered. How this knowledge is transmitted is unclear. Furthermore, when contractors encounter claims for technologies that are not included in the coverage issues appendix and which raise issues of national importance because they are experimental or potentially costly, the contractors are expected to ask HCFA for a national coverage determination. However, the criteria for identifying such technologies are not well specified.

Technologies Not Covered by HCFA

For some technologies, HCFA's Office of Coverage Policy expects that claims will be denied, even though there is no HCFA policy explicitly denying coverage. For example, some sections of the coverage issues appendix state that technologies will be covered *only* in specified circumstances, meaning by implication, that all other uses of the technology will not be covered. The use of biofeedback for intractable pain is the only study technology to fall into this category. Section 35-27 of the coverage issues appendix states:

> Biofeedback therapy is covered under Medicare *only* when it is reasonable and necessary for the individual patient for muscle reeducation of specific muscle groups or for treating pathologic muscle abnormalities of spasticity. . .(etc.). . . This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions.

Fifty-five percent of the contractors follow HCFA's intent and reported that they would not cover biofeedback therapy for intractable pain. Reasons given for approving coverage with qualifications include: documentation that all other methods have failed, when used in conjunction with physical therapy, when part of a pain rehabilitation center program, and when used for specific muscle reeducation. (The final qualification listed may indicate that the respondent misunderstood the question. Although specific muscle reeducation would be a reimbursable use of biofeedback, that is not what the question addressed.)

The questionnaire included two other technologies which are not explicitly denied coverage, but for which HCFA believes the contractors should understand that coverage should be denied. In both instances, other uses of the same technology are specifically covered. According to HCFA, percutaneous transluminal coronary angioplasty (PTCA) to eliminate obstruction in two or more coronary arteries should not be covered, even though a single vessel procedure is covered. Almost 52 percent of the respondents would not approve a claim for PTCA involving two or more arteries, while about 38 percent would approve the claim, either with or without qualifications. The reported qualifications suggest that the contractor would review each case individually to determine medical necessity, that the criteria specified for a single-vessel procedure would be applied, that the claim would be approved only if the requested charges were reasonable, and that the claim would be approved, but the level of reimbursement would be the same as for a single-vessel procedure. Presumably, the HCFA restriction on multiple-vessel procedures was based on a concern for increased patient risk; however, it does provide an opportunity for "creative" billing.

The other instance in which coverage should be understood to be denied is the use of apheresis (therapeutic apheresis) or plasma exchange in the treatment of systemic lupus erythymatosis (SLE). Therapeutic apheresis is covered for several indications listed in the coverage issues appendix, but not for systemic lupus. In May 1983, PHS tentatively recommended that apheresis for SLE should not be covered; however, that recommendation was withdrawn and the issue will be reconsidered. This uncertainty is reflected in our responses. Sixty percent of the contractors do not cover apheresis for patients with SLE, while 18 percent would cover without restriction, and another 14 percent would cover with qualifications.

The final category of technologies includes those for which HCFA policy explicitly denies coverage. The highest adherence to that policy is seen in claims for chelation therapy with EDTA in the treatment of atherosclerosis and for topical oxygen therapy (e.g., using a Topox device) in the treatment of decubitus ulcers. The lower rate of claims denial for a pacemaker device for a patient with sinus bradycardia without symptoms may reflect the policy of at least some contractors to submit all pacemaker claims to indepth medical review, prior to making coverage determinations. The primary reason for covering electroencephalographic (EEG) monitoring during open-heart surgery was documentation by a physician that it was needed. Some contractors noted the difficulty of determining whether a monitor was used, indicating that they do not usually receive a separate bill for this, but that the bill for the surgery may be somewhat inflated.

The responses for continuous 24-hour monitoring of blood pressure reflect, in part, changing HCFA policy. Use of a semiautomatic or patient-activated portable monitor had been specifically not covered since October 1982. However, there was no explicit policy regarding coverage of the automatic, continuous monitoring device until July 1983, when coverage was explicitly denied. Some respondents may not have been aware of this recent policy issuance. Furthermore, some respondents appear to have confused the automatic device in the question (which includes a sensing apparatus and provides continuous monitoring and recording) with an automatic blood pressure monitor that can be covered, if prescribed by a physician for use as part of a home dialysis delivery system. Reimbursement for the latter is limited to the amount which would be payable for a sphygmomanometer with cuff and stethoscope unless there is documentation that the patient's condition is such that conventional methods of monitoring are not successful. Both potential sources of confusion may have resulted in a greater tendency to approve coverage of automatic, continuous, 24-hour blood pressure monitors than would have been expected.

In summary, it appears that with the exception of intraocular lens implantation, there is variation in coverage decisions made by Medicare contractors, regardless of HCFA policy. Interpretation of the variation is complicated by the dependence of coverage policy on consensus within the medical community that a given technology is safe and effective. If that consensus is lacking or just emerging, it might be expected that a coverage policy, if one existed, would be lacking in specificity and inconsistently adhered to by contractors. Nevertheless, differences in coverage decisions by Medicare contractors appear to be related to the clarity or specificity of HCFA policy. The variation is least in some instances in which HCFA has explicitly approved coverage. Variation is much greater for technologies that HCFA intends to be denied, but for which there is no explicitly stated denial policy, as well as technologies for which coverage policy is changing. In most instances, however, the majority of contractors adhere to HCFA's intentions.

Contractor's Views and Interpretation of HCFA Coverage Policy

Several questions explored the contractor's perceptions of HCFA coverage policy and the processes by which it is promulgated. For example, the respondents were asked how frequently HCFA coverage transmittals can be implemented as written, rather than requiring further interpretation. As shown in table E-7, over half the respondents indicated that HCFA transmittals can always or almost always be implemented as written. When further clarification is needed, the sources of assistance tend to be the same as those utilized in making any coverage determination (see table E-4).

It was noted earlier that about 88 percent of the respondents indicated that they utilize HCFA's regional office in their area for assistance in making coverage decisions. To ascertain whether there is any predictability in the types of coverage questions referred to the regional office and, perhaps, to HCFA's central office, the contractors were asked whether they used any criteria to determine when to refer a coverage question to HCFA. The responses generally fell into two categories. Some contractors appear to use the regional office rather routinely if the coverage issues appendix does not address the technology in question, HCFA policy is ambiguous, the contractors are not familiar with the technology, or "we don't know what to do." Other contractors attempt to establish their own policies and use the regional office as a last resort, i.e., only if their own decisions have been challenged by providers or if a technology is experimental and has a potential for abuse. Some contractors are guided by

Table E-7.—Medicare Contractors' Attitudes and Actions Regarding HCFA Coverage Transmittals

	Contractors' response					
	Never	Rarely	Sometimes	Almost always	Always	Number of responses
HCFA coverage transmittals can be implemented as written rather than requiring further interpretation	7.1%	7.1%	30.4%	35.7%	19.6%	56
Contractor informs HCFA regional office of its interpretations of HCFA policy	10.6	25.5	14.9	—	48.9	54
	More	Same	Less	Not applicable		Number of responses
Specificity of HCFA policy compared with policy for other claims reviewed by contractor	35.7%	26.8%	3.6%	33.9%		56

SOURCE: L. K. Demlo, G. T. Hammons, J. M. Kuder, et al., "Report of a Study on Decisionmaking by Medicare Contractors for Coverage of Medical Technologies," prepared for the Office of Technology Assessment, U.S. Congress, Oct. 28, 1983.

the advice of their onsite HCFA representatives about when to refer coverage questions to the regional office.

When contractors take the initiative to further interpret HCFA coverage policies themselves, most of them inform HCFA's regional office of their interpretation (see table E-7). Of those respondents, most have onsite HCFA representatives to whom they automatically send copies of their policy interpretations.

When comparing HCFA coverage policy with policies governing other health insurance claims reviewed by the contractor, most contractors report that HCFA policy is as specific or more specific than policies for other insurance claims (see table E-7). About one-third of the contractors were unable to answer the question, because they review only Medicare claims and had no basis for comparison.

Interrelationships Between Coverage Decisions and Contractor Characteristics

To better understand the extent to which characteristics of Medicare contractors and their claims review processes may influence coverage decisionmaking, several additional analyses were performed. The responses about coverage of individual technologies were categorized according to whether the respondent organization was an intermediary or carrier, whether the contractor was a commercial insurance company or a Blue Cross or Blue Shield plan, and according to the contractor's geographical location, the discipline and position of the individual respondent, claims volume, and the contractor's reasons for and willingness to refer coverage questions to the regional office. Occasionally, statistically significant differences emerged; however, no meaningful trends were observed for any of these analyses.

Contractors' Suggestions for Improving Coverage Transmittals

Given the importance of HCFA transmittals in shaping coverage decisions, the respondents were asked to suggest specific changes that might improve either the process by which HCFA coverage policies are transmitted to Medicare contractors or the content of those coverage policies. The timing of HCFA coverage transmittals is the primary concern of respondents. A majority of them cite difficulties in implementing transmittals simply because they lack adequate lead time to prepare their organizations; some transmittals arrive after the date on which they were to become effective. Suggested improvements include increasing reliance on interim memos and guidelines transmitted prior to the final directive, as well as simply lengthening the lead time for implementation and eliminating retroactive policies.

Many contractors note a need for greater national consistency in interpreting coverage policies. They mention differences in policy interpretations among HCFA regional offices, which may increase contractors' vulnerability to litigation and are particularly troublesome for large commercial insurance companies that serve as carriers in several States. They also note instances in which a single contractor receives a policy determination from HCFA's central office in response to an inquiry; that is not shared nationwide, the result being inconsistent interpretation of coverage policy. These problems, as well as inadequate local resources for contractors to pursue the status of new technologies themselves, lead many contractors to recommend the creation of a national coverage clearinghouse. Such a clearinghouse, perhaps supported by the Government, insurance companies, and medical and specialty associations, could disseminate information on new technologies, the status of their evaluation, and implications for coverage policies. It should also be noted, however, that many contractors are quite content with the status quo and prefer to utilize local resources in making their own coverage decisions.

Another area of concern is the specificity of HCFA coverage transmittals. Contractors report that the policies are too technical, too ambiguous, and lacking in specificity. The need for more specific criteria for covering durable medical equipment was frequently mentioned, as well as the need to update all references to a specific technology in order to eliminate inconsistencies within the coverage issues appendix and manual. Several respondents note that the content of coverage transmittals is improving, citing the policy covering pacemakers as a good example. On the other hand, one respondent cited the pacemaker issuance as indicative of the failure of HCFA's central office to understand the claims review process. In this respondent's opinion, the policy governing pacemakers does not take into consideration the process by which claims are submitted and the information included on the claim, making it impossible to process the claim without extensive and expensive investigation. Some contractors thought that these issues were not worth debating, because Medicare's move to prospective payment will render any changes outdated or useless. Still others felt the coverage issues appendix is clear and sufficient and that the coverage system as a whole works "remarkably well."

Summary and Conclusions

This study has confirmed the conventional wisdom that there is variation in the decisions made by Medicare contractors regarding the coverage of particular medical technologies. There are high levels of agreement and near unanimity in coverage decisions for some study technologies—particularly for intraocular lens implant following cataract removal (98.2 percent covered), the use of chelation therapy in the treatment of atherosclerosis (87.0 not covered), and the use of topical oxygen therapy for decubitus ulcers (86.3 percent not covered). However, there are also examples of wide variations in coverage policies—particularly for a pacemaker device and its implantation for a patient who has sinus bradycardia without symptoms, an implantable chemotherapy infusion device for a patient with metastatic to the liver cancer, and external insulin infusion pump for a diabetic patient, and streptokinase administration at cardiac catheterization to dissolve a clot in a patient with acute myocardial infarction.

Despite these variations in coverage policies, there is considerable uniformity among contractors in the methods by which claims are reviewed and national coverage decisions are implemented. After an initial review for completeness, most claims pass through (potentially) three levels of review that reflect differing degrees of comprehensiveness, specificity, and clinical judgment. The levels of review generally involve clerical employees, registered nurses, physicians, or some other health professionals (pharmacist, podiatrist, occupational therapist, etc.) in that order. Although the specifics may vary, general considerations at each level of review are similar, as are the criteria for referring a claim from one level of review to the next. Eighty-four percent of the respondents use some type of automated screening procedure. When revisions or additions to the coverage issues appendix are received from HCFA, most contractors review them internally and modify their claims review procedures accordingly. Coverage issues requiring further clarification are pursued either locally or nationally; HCFA's regional offices are the most frequently utilized sources of clarification and interpretation.

Similarly, the methods by which contractors identify new technologies or new uses of established technologies are quite predictable. Most contractors report that they learn about new technologies for which coverage questions might be raised through inquiries from providers and manufacturers prior to the actual submissions of claims, drug and device approval lists from FDA, and HCFA announcements. Once claims are submitted, new technologies are identified because of the absence of code numbers or the presence of codes that are not recognized by the claims reviewers. Although a few contractors conduct extensive research to assist in identifying and making coverage decisions for such claims, the majority assume a more passive role. The majority are reasonably well satisfied with existing methods for identifying new technologies and report that this is not a big problem for them. Making coverage determinations for new technologies is a problem, however.

Some characteristics of the contractors included in the study did vary. The respondents include a mix of intermediaries and carriers; some are commercial insurance companies and others are BC/BS plans; they come from different geographic locations, handle different volumes of claims, and show different tendencies and reasons for referring coverage questions to HCFA's regional office, rather than attempting to resolve the issue themselves. Nevertheless, these characteristics were not systematically related to variations in coverage decisions in any meaningful way.

The most illuminating approach to examining variations in coverage decisions was based on coverage policy, according to the following categories: technologies that HCFA explicitly covers; those that HCFA covers with qualifications; technologies that HCFA explicitly denies; those that HCFA denies, but not explicitly; and those for which HCFA has no explicit policy, but rather, the local contractor is expected to determine coverage policy. There is variation in every category of HCFA coverage policy, with the possible exception of claims for intraocular lens implantation. Interpretation of that variation is complicated by the dependence of coverage policy on consensus within the medical community that a given technology is safe and effective. If that consensus is lacking or just emerging, it might be expected that a coverage policy, if one existed, would be lacking in specificity and inconsistently adhered to by contractors. Nevertheless, the differences in coverage decisions by Medicare contractors appear to be related, at least in part, to the clarity or specificity of HCFA policy. The variation is least in instances in which HCFA has explicitly approved coverage. Variation is much greater for technologies that HCFA intends to be denied, but for which there is no explicitly stated denial policy, as well as technologies for which coverage policy has recently changed or is expected to change. Despite the variation, however, when the responses for individual technologies are analyzed, the preponderance of respondents tend to adhere to HCFA intentions.

If less variation in coverage decisions is desired, the study findings suggest some ways in which this might be accomplished. Greater specificity and uniform interpretation of wording would help to lessen the uncertainty about the technologies that HCFA intends to be denied, but for which denial is not explicitly stated in written policy. Similarly, uniform and more timely communication from HCFA might lessen the variation in coverage for technologies that are currently being reviewed by PHS or for which policy is expected to change. The respondents' suggestions about a national coverage clearinghouse should also be considered.

Reducing variation in coverage decisionmaking should help to eliminate any existing inequities in the availability of benefits to persons eligible for Medicare. To the extent that a technology is not intended to be covered, greater adherence to HCFA policy would also save money. If changes in coverage policy are intended to influence the proliferation and use of medical technology so as to result in significant cost savings, however, more major revisions are needed in the way in which coverage determinations are made. The cost effectiveness of technologies would have to assume a more prominent role in coverage deliberations, as well as the possibility of limiting the health care settings and providers who would be eligible to claim reimbursement.

The potential for increased equity of benefits and financial savings that might accrue from more uniform coverage decisions must be balanced against the potential negative effects. It is unlikely that any nationally determined, uniform coverage policy can ever take into consideration the uniquely personalized needs of all patients. In some small number of cases, increased uniformity of coverage probably would occur at the expense of quality of care. Carried to the extreme, increased explicitness of coverage policy may have a negative effect on access to care and the potential for innovation in medicine. Furthermore, the costs of implementing and enforcing a uniform system might outweigh the advantages.

In the final analysis, the decision to reduce variation in coverage policy and increase the explicitness and uniformity of Medicare benefits requires careful judgment and balance. Some lessening in that variation appears to be desirable and achievable, provided it is carefully coordinated with forthcoming changes in the overall reimbursement system. However, it is unlikely that HCFA policy can ever be so precise as to achieve a totally uniform interpretation and implementation of Medicare coverage policy throughout the Nation.

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